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A Significant Improvement in a Clinical Pilot Study Utilizing Nutritional Supplements, Essential Fatty Acids and Stabilized Aloe Vera Juice in 29 HIV Seropositive, ARC and Aids Patients.

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ABSTRACT: It has been found that poor nutrition is one of the risk factors for progressing from HIV seropositive into ARC and into AIDS. By improving the patient's nutritional status the possibility of progressing into AIDS Related Complex (ARC) or Acquired Immune Deficiency Syndrome (AIDS) may be reduced or at least delayed, and the goal is to place the patient into long term remission.¹ To attempt to accomplish this end, a powdered nutritional supplementation was provided to study participants together with essential fatty acids and stabilized 100% pure Aloe Vera Juice for a study period of 180 days.² At the conclusion of the study, the participants had improved both clinically and functionally. Most patients who were symptomatic reported that within three to five days their symptoms had subsided and they had gained weight. This regimen of nutritional supplementation is cost effective and non-toxic and can be an important factor in halting the progression of the HIV virus by boosting the immune system, decreasing the P24 core antigen activity and improving the overall quality of the patient's life.

Introduction

The possible beneficial effects of a balanced nutritional supplementation,³⁻⁵ including essential fatty acids (EFA)⁶⁻⁹ and Aloe Vera Juice in HIV seropositive asymptomatic, ARC, and AIDs patients was studied in an open trial in 30 patients. In this study, which combined all three of these food substances, the specific objectives were to determine if this combined treatment regimen caused remission or regression or helped to prevent the progression of this disorder as evidenced by physical signs, laboratory measures and subjective reports.¹⁰⁻¹²

Patients and Methods

The study protocol and patient consent form were approved by the Dallas/Fort Worth Medical Center at Grand Prairie, Texas, Investigational review Board (IRB). Reports were made to the IRB at three month intervals and at the conclusion of the study.

The study protocol required that an initial 30 patients be selected and studied for a period of 180 days. In order to enter the study the patients had to meet the following criteria:

Ambulatory patients, age greater than 18 years; diagnosed as HIV seropositive asymptomatic, ARC or AIDS; sign a valid informed consent as approved by the IRB; demonstrate positive HIV antibody testing (ELISA) confirmed by Western Blot; T-4/T-8 lymphocyte ratio of less than 1; and Karnofsky Quality of Life Assessment score (KQLA) of 20 or greater.

There were no current exclusion criteria to entering this study except for inability or unwillingness to comply with the protocol, or sign the informed consent. Hypersensitivity to the food supplements would have precipitated immediate termination from this study. At the initiation of the study, patients were excluded if their T-4 count dropped below 12, since the disease was considered too advanced of if they were receiving treatments which might interfere with determining the effectiveness of the study protocol.

No chemotherapeutic agents or radiation therapy could be given simultaneously for the patient to remain an active participant. Immunization to tetanus, influenza (Fluzone 0.5 cc.) and pneumonia (Pneumovax 0.5 cc.), were to be current. The patients were allowed to continue with all other medication regimens, including AZT. (Table 1).

Patients entered into the study were asked to take the following nutritional supplements during the the study; Essential Fatty Acids (EFA) Capsules, 2 capsules, 4 times a day; Aloe Vera juice, 5 ounces, 1 times a day and 1 level scoop of nutritional supplementation powder, 4 times daily in water. (Tables 2-4) The patients were encouraged to continue to eat their regular diet, allowing the nutritional supplements and aloe vera to be the only change in diet.

TABLE 1
Drugs the Study Participants Were Taking When They Entered the Study

Patient	AZT	Pentamidine	Zovirax	Other	None Dropped
1				INH/Ethambutol Daily (Military TB) Stereptomycin, 1 gm 2 x wk PZA, 1500 mg. Q.D.	
2	200 MG. Q 4 Hours	150 mg. Q 2 weeks	200 mg. TID (Chronic EBV)		
3		150 mg. Q 2 weeks		ETOH/Cigarettes	
4				Accutane; ETOH/Cigarettes	
5		300 mg. Q mo	200 mg. TID (EBV)	Completed CHOP/Liver chemotherapy for Primary Lymphoma	
6					X
7			200 mg. 5 caps Q 8 hr.		
8					X

9						X
10						X
11					ETOH	
12		300 mg. Q mo.			INH	
13	AZT induced anemia (d/c'd on start in study)					
14		300 mg. Q mo.			Nizoral 200 mg. Q D (Onychomycosis)	
15		300 mg. Q mo. (AIDS dementia)				
16			200 mg. (EBV)			
17						X
18					Isoprinosine 500 mg., 2 p.o., TID	
19						X
20	200 mg. Q 4 hr.	300 mg. Q mo			Mycelex; ETOH	
21	None, AZT failure	300 mg. Q mo.				
22						(had KS) P24 core antigen dropping from 9 to 4
23					ETOH/Cigarettes	
24	AZT (Aug-Oct 88), dc'd three months into the study	300 mg. Q mo.				
25					ETOH/Cigarettes + for Marijuana	
26		150 mg. Q 2 wk S/P PCP			ETOH/Cigarettes; + Marijuana Nizoral 200mg. QD ETOH; + for Marijuana	
27	100 mg. Q 4 hr	150 mg. Q 2 wks	200 mg. Q 8 hr			
28					Nizoral 200 mg; ETOH/Cigarettes	
29					ETOH/Cigarettes	
30						X
31					+ for Cocaine on Drug Screen	

TABLE 2

GLA/EPA Capsule Ingredients

Linoleic Acid (LA)	280 mg
Gamma Linolenic Acid (GLA)	80 mg
Eicosapentaenoic Acid (EPA)	45 mg
Docosapentaenoic Acid (DPA)	9 mg
Docosahexaenoic Acid (DHA)	30 mg
d'alpha tocopherol	15 mg

The powdered supplement exceeded the recommended daily allowance (RDA) by about 200%.¹³⁻¹⁵ However, the concentration of vitamin A was well below the theoretical toxic level of 50,000 units a day, and that of vitamin D was well below the projected toxic level of between 150 and 300,000 units/day.¹⁶ The protein source was adequate for all essential amino acids and the supplementation as described in the study was found to be well within the margin of safety. Each patient received monthly supplies of the nutritional supplements. Medications other than the study nutrients were to be provided by the patient's physician and/or the study physician as the subject's condition appeared to require, with accurate record keeping of dosages and schedules. The patient's personal physician was kept fully informed. Patients were also asked to refrain from any other supplements or vitamins. They were also required to practice safe sex guidelines throughout the study, and were aware that they could withdraw from this study for any reason, any time.

The study of any individual was to be discontinued if it was obvious that there was rapid deterioration in the clinical condition.

TABLE 3
Powder Ingredients

Nutritional Information per serving

Serving Size	48 grams	Fat	1 gm
Calories	160	*Cholesterol	0 gm
Protein	13 gms	Sodium	120 mg
Carbohydrates	26 gms	Potassium	660 mg

Percentages of U.S. Recommended Daily Allowances (U.S. RDA) per serving:

Protein	30%	Vitamin E	50%	Copper	50%
Vitamin A	70%	Vitamin B ₆	50%	Biotin	50%
Vitamin C	50%	Folic Acid	50%	Pantothenic Acid	50%
Thiamine	50%	Vitamin B ₁₂	50%	**Chromium	23 mcg
Riboflavin	60%	Phosphorus	20%	**Selenium	23 mcg

Niacin	50%	Iodine	50%	**Manganese	2 mg
Calcium	25%	Magnesium	50%	**Fiber	3 gms
Iron	50%	Zinc	50%	**Octacosanol	2000 mcg
Vitamin D	50%				

Amino Acids per 48 gram serving

Alanine	375 mg	Histidine	320 mg	Proline	1425 mg
Arginine	450 mg	Isoleucine	655 mg	Serine	700 mg
Aspartic acid	850 mg	***Leucine	1115 mg	***Threonine	510 mg
Cystine	65 mg	***Lysine	920 mg	***Tryptophan	145 mg
Glutamic acid	2640 mg	***Methionine	310 mg	Tyrosine	630 mg
Glycine	250 mg	***Phenylalanine	600 mg	***Valine	755 mg

Ingredients: Fructose, Nonfat Milk Solids, Calcium Sodium Caseinate, Natural and Artificial flavors, Cellulose, Corn Bran, Potassium Chloride, Lecithin, Maltodextrin, Carrageenan, Wheat Germ Oil, (source of Octacosanol), Magnesium Oxide, Beta Carotene, Selenium, Ascorbic Acid, Ferrous Fumarate, d'Alpha Tocopherol Acetate, Chromium, Niacin, Aloe, Apple Pectin, Zinc Oxide, Manganese Sulfate, Vitamin A Palmitate, d-Calcium Pantothenate, Copper Sulfate, Pyridoxine Hydrochloride, Riboflavin, Thiamine Hydrochloride, Cobalamin Concentrate, Vitamin D₂, Folic Acid, Biotin and Potassium Chloride.

* Information on cholesterol content is provided for individuals who, on the advice of a physician are modifying their dietary intake of cholesterol.

** No RDA established for these nutrients.

***Essential Amino Acids

TABLE 4
Aloe Vera Juice Ingredients

The Aloe Vera Juice is produced from the crystal clear gel of Aloe barbadensis Miller fresh leaves by an extraction and purification process.

SPECIFIC GRAVITY:	1.00 - 1.002
SOLIDS:	minimum of 0.30%
pH VALUE:	3.5 - 5.0
CONSISTENCY:	slightly viscous
PATHOGENS:	none
CALIFORMS:	none

POLYSACCHARIDE CONTENT:	minimum 1200 mg/liter
PRESERVATION:	0..25% stabilized electrolytes of oxygen (non-toxic) 0.07% potassium sorbate

Clinical Evaluation

Each subject was initially seen for a thorough medical evaluation and laboratory studies, and repeated at 30, 60, 90 and 180 days throughout the study. This consisted of a complete physical examination, laboratory studies, including chest x-ray, EKG, white blood cell count with differential and sedimentation rate. Blood pressure, temperature, pulse, and respirations, as well as weight were recorded at each visit during the study.

Episodic interval care, including any additional laboratory studies for other conditions which could have significant impact, if required, were recorded. (Table 5). A sexual practice questionnaire was gathered (Table 6). A Modified Walter Reed Clinical Evaluation was calculated at each visit.¹⁷ (Table 7). The modified version was selected because it contained more criteria and allows for evaluation up to 14; the standard Walter Reed scores only up to 6. The Modified Walter Reed score was ranked 1 for each parameter noted. A score of 6 or greater was equivalent to AIDS, while ranking 2 to 5 was ARC, ranking 0 to 2 was HIV positive, asymptomatic. In addition, any lymphadenopathy was recorded and a T-4 count less than 400 was noted. Delayed skin hypersensitivity (DHS) to skin testing was evaluated.

TABLE 5
Opportunistic Infections, Cancer, RPR Positive and Other Conditions Present Initially or During the Treatment of the Study Participants,

Patient	Opportunistic Infections	Cancer	Other Conditions	None	Dropped
1	Military TB				
2	S/P PCP		EBV		
3				X	
4				X	
5		Primary Liver Lymphoma	EBV		
6				X	
7			Chronic herpes		
8					X
9				X	
10				X	
11				X	
12	Military TB (Rx'd)	Kaposi's Sarcoma, 7-24-89, Cutaneous			

13	AIDS Wasting Syndrome		Anemia Secondary to AZT		
14				X	
15			Herpetic Zoster/AIDS Dementia		
16			EBV		
17			AZT induced Anemia		
18				X	
19				X	
20			Venereal Warts		
21	S/P PCP		AZT induced Anemia		
22		Kaposi's Sarcoma, widespread, cutaneous			X
23				X	
24	S/P PCP				
25				X	
26	S/P PCP				
27	S/P PCP		Anal Condyloma; Herpetic Proctitis; CMV		
28			ITP, S/P SPLENEETOMY Nov '85		
29				X	
30				X	
31				X	

TABLE 6
Sexual Practices of Study Participants

Patient	Homosexual	Heterosexual	Healthcare worker	Caraloe as only aloe	Dropped from study
1	Receptive, Anal			X	
2	Safe sex, Receptive, Active			X	
3	Safe sex			X	
4	Oral sex				
5	Safe sex, Monogamous,- Partner			X	
6		Safe sex	Orthodontist	X	

7	Receptive	Physician		
8				X
9	Safe sex		X	
10	Safe sex			
11	Safe sex			
12	Safe sex, Monogamous			
13	Safe sex, Monogamous			
14	Active			
15	Receptive, Anal		X	
16	Receptive, Active		X	
17	Safe sex, Active, Anal			
18	Safe sex, Monogamous, + Partner			
19	Safe sex, Multiple			
20	Non-monogamous + Partner			
21	Celibate			
22				
23	Safe sex, Monogamous, - Partner			
24	Safe sex, Monogamous, + Partner (AIDS)			
25	Safe sex, Active, Anal, Oral, Multiple partners			
26	Safe sex, Anal, Oral			
27	Celibate			
28	Unsafe sex-'84; Safe sex-now, Anal, Rimming, Oral-until-'84		X	
29	Celibate 2 1/2 yrs; always anal receptive before			
30	Safe sex, Multiple partners			
31		Safe sex		

TABLE 7

Modified Walter Reed Clinical and Calculation Form Example

PATIENT ID. _____		TERRY PULSE, M.D.	
Patient ID _____		Signature _____	Date _____
		OTHER INDIVIDUAL PATIENT CLINICAL PARAMETERS	
Lymphadenopathy	<input type="checkbox"/>	Persistent Fatigue	<input type="checkbox"/>
T-4 Abs Count (less than 400) Enter actual value	<input type="checkbox"/>	Night Sweats	<input type="checkbox"/>
Delayed Skin Hypersensitivity (DHS)	M	Documented Fever	<input type="checkbox"/>
	C		
	TPP		
Thrush	<input type="checkbox"/>	Persistent or Episodic Diarrhea	<input type="checkbox"/>
Opportunistic Infections	<input type="checkbox"/>	WBC	<input type="checkbox"/>
P24 Core Antigen	<input type="checkbox"/>	SED RATE	<input type="checkbox"/>
Other _____	<input type="checkbox"/>	Lesion (K.S.)# and shape	<input type="checkbox"/>
TOTAL SCORES _____			

TABLE 8

Karnofsky Quality of Life Assessment Form

Description	Scale %
* Normal, no complaints, no evidence of disease	...100
Able to carry on normal activity, minor symptoms or signs of the disease	...90
* Normal activity with effort, some signs or symptoms of the disease	...80
* Cares for self, unable to carry on normal activity	...70

	or	
*	do active work	
	Requires occasional assistance, but is able to cater	...60
*	for most of his needs	
	Requires considerable assistance and frequent	...50
*	medical care	
*	Disabled, requires special care and assistance	...40
	Severely disabled, hospitalization is indicated	...30
*	although death is not imminent	
	Hospitalization necessary, very sick, active	...20
*	supportive treatment necessary	
*	Moribund, fatal processes progressing rapidly	...10

Score *

| ____ / ____ / ____ | %

*(any intermediate value, one item only)

The antigens used were Mumps, Candida, Trichophyton, Tuberculin Purified Protein Derivative (TPP) and a saline control. The patient with a fully functioning immune system should react to all antigens, except for TPP unless they have an active case of Tuberculosis. Thrush, or any other opportunistic infections were catalogued. Unusual persistent fatigue, night sweats, documented fever and persistent or episodic diarrhea at the time of entry into the study were noted and the location, shape and number of Kaposi's sarcoma lesions recorded. Any clinical or laboratory data furnished by a subject's personal physician were also recorded. A Karnofsky Quality of Life score was calculated initially, and at 180 days.¹⁸ (Table 8). The Karnofsky Quality of Life Assessment score is ranked by the patients themselves, based on their ability to function adequately at day one and day 180.

Laboratory Evaluation

Laboratory examinations performed at the initial evaluation were the Diagnostic Reflex Panel II, which included a CBC with differential, SMAC-24, thyroid studies with TSH, sedimentation rate, Rapid Plasma Reagin Test (RPR), T cell subsets by flow cytometry, and P24 core antigen assay. At each subsequent visit, laboratory examinations performed included a complete blood count with differential, platelet count, sedimentation rate, SMAC-24, a lymphocyte enumeration panel and a T4/T8 ratio. Other tests were performed as required, depending upon the clinical state.

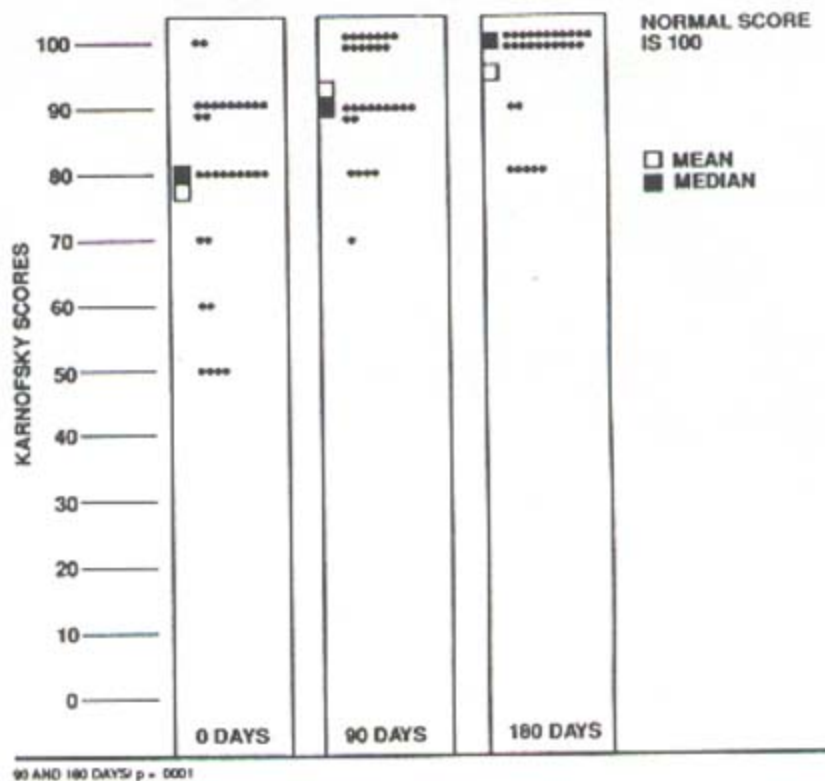
It was agreed that there might be six to twelve month extension of the study for any individual who had derived benefit, if he so desired.

Results

Initially, 31 patients were to be studied, of whom 2 dropped from the study for non-compliance. Of the 29 remaining, 15 had an initial Walter Reed scores consistent with a diagnosis of AIDS, 12 met the criteria for ARC and 2 were HIV seropositive but asymptomatic. Modified Walter Reed scores on initial evaluation showed a median of 6.25 and a mean of 5.39; at 90 days the evaluation period showed a median drop to 1.50 and a mean drop to 2.0. The Modified Walter Reed score shows improvement when it decreases. All 29 of the patients had lower Modified Walter Reed scores at 90 days for 100% improvement as a group; at 180 days 2 remained the same and 27 improved further for 96.4% improvement. Although statistical significance was shown at 90 days ($p = 0.0001$), at 180 days the scores on the Modified Walter Reed were significantly lower than the initial scores. ($p = 0.0001$ on both the Wilcoxon Signed Rank Test and the t-test). Karnofsky Quality of Life assessment scores were done initially with a median of 80 and mean of 78.97 and at 90 days the median was 90 and the mean was 92.41. The Karnofsky Quality of Life Assessment shows improvement when it increases. Twenty seven patients improved on the Karnofsky score at 90 days and two remained the same for 93.1% improvement; all improved at 180 days for 100% group improvement.

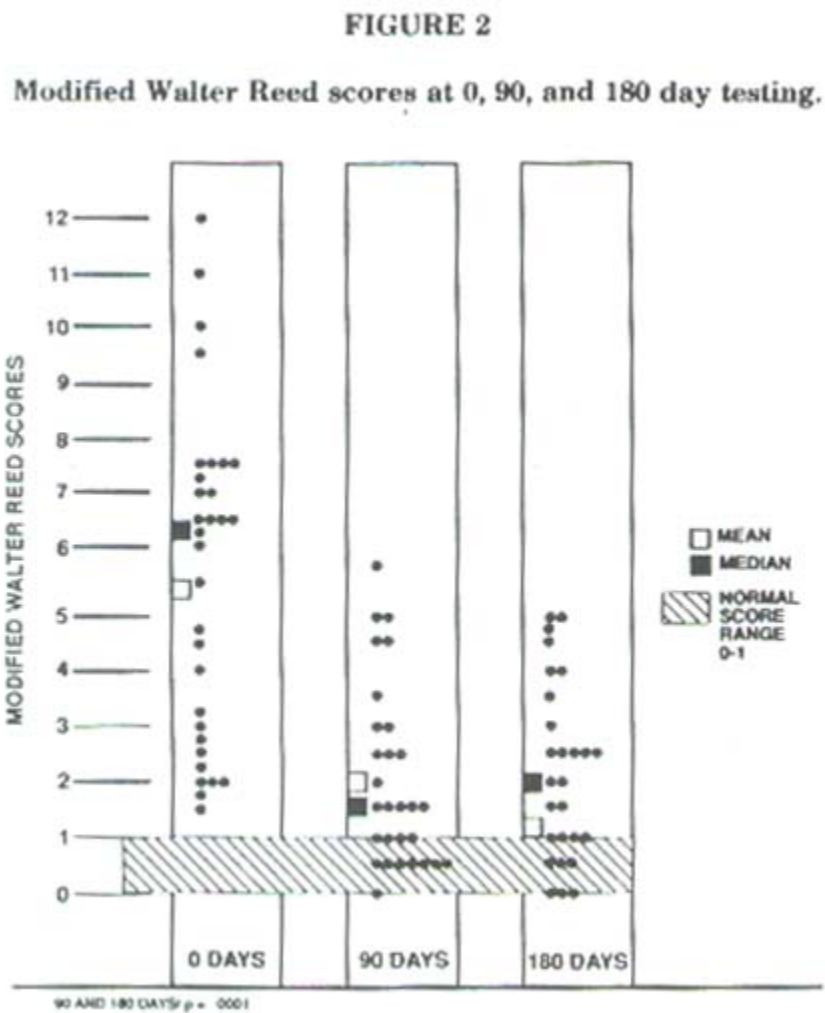
FIGURE 1

Karnofsky quality of life scores at 0, 90, and 180 day testing.



(Figure 1) Again, although statistical significance was shown at 90 days ($p = 0.0001$), at 180 days the scores were significantly higher than the initial scores. ($p = 0.001$ on both the

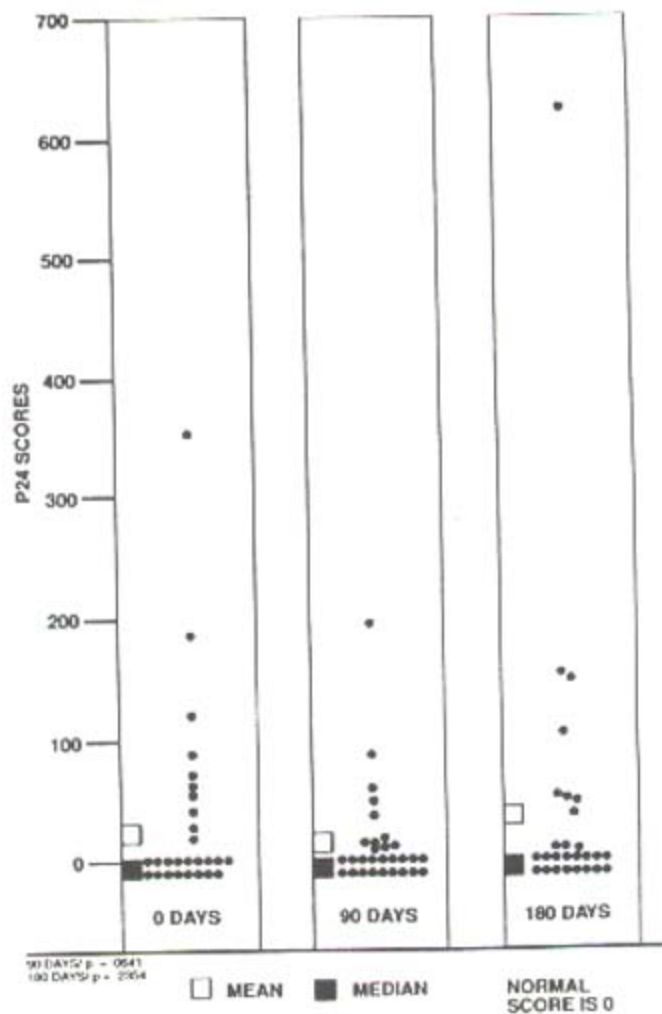
Wilcoxon Signed Rank Test and the t-test). (Figures 1,2). Of greatest significance was the P24 core antigen assay in which at 90 days 3 out of 12 (25%) of those that were originally positive for the P24 core antigen had converted to nonreactive (not due to spontaneous deterioration of a failing immune system or end stage AIDS); at 180 days this figure remained the same. The P24 core antigen is a measurement of viral replication. Although not all patients present positive for P24, a reduced or negative P24 is desired.



The P24 was statistically significant on the Wilcoxon Signed Rank Test at 90 days and showed a trend on the t-test at 90 days. At 90 days the P24 value indicated a statistical improvement over the initial measurement. (Figure 3).

FIGURE 3

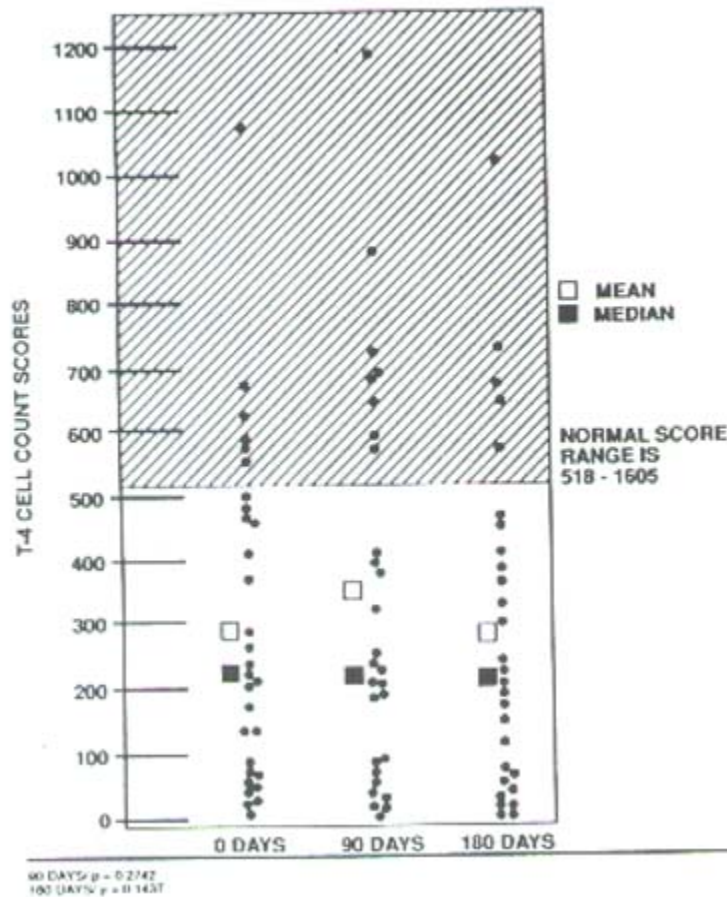
P24 scores at 0, 90, and 180 day testing.



The T4 helper lymphocytes at 90 days increased in 15, decreased in 12 and remained unchanged in two. At 180 days 9 had increased and 19 had decreased. Theoretically, the higher the T4 count the healthier the person. Because of the wide range of values in the normal range for T4 helper lymphocytes, the number of the patients with increased T4 lymphocyte counts was compared to the number decreased.

FIGURE 4

T-4 cell count at 0, 90, and 180 day testing.

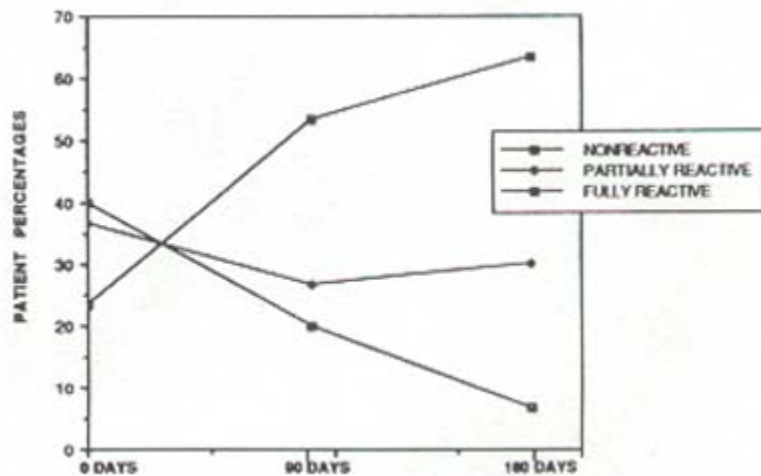


Statistically, No exact statistical difference occurred in the T4 counts (T4/90 $p = 0.2742$, T4/180 $p = 0.1437$) (Figure 4). Hypersensitivity skin testing to all antigens improved in 10 patients at 90 days and 19 of them had fully restored delayed hypersensitivity (63.3%) at 180 days. the desired result was fully restored delayed hypersensitivity. (Figure 5).

FIGURE 5

Delayed hypersensitivity testing results. Nonreactive: 0 days, 12(40%); 90 days, 6(20%); 180 days, 2(6.6%). Partially reactive: 0 days, 11(36.6%); 90 days, 8(26.7%); 180 days, 9(30%). Fully reactive: 0 days, 9(23.3%); 90 days, 16(53.3%); 180 days, 19(63.3%). Three hypotheses were tested and rejected at a significance level of 0.5. Ho1: There is no difference in the reactivity of patients at the initial and 90 day testing. Ho2: There is no difference in the reactivity of patients at the initial and 180 day testing. Ho3: There were no changes over time in the reactivity of patients. The difference in reactivity in the initial and 90 day testing was statistically significant

(Chi Square = 5.9954, $p = .0499$). Statistically fewer patients were non-reactive and partially reactive and more patients were fully reactive than initially. The difference in reactivity in the initial and 190 day testing was statistically significant (Chi-Square = 12.8813, $p = .0016$). Significantly fewer patients were non-reactive and partially reactive and more patients were fully reactive than initially. The test results involving Ho3 looked at the initial, 90 day and 180 day results simultaneously and concluded that there was a statistically significant shift to more reactivity over time (Chi-Square = 13.6714, $p = .008$).



No adverse effects were attributable to the nutritional supplements. Most of the symptomatic patients reported that within three to five days their energy level improved, fever disappeared, night sweats stopped, cough decreased or stopped altogether, shortness of breath decreased, lymph nodes decreased in size, diarrhea stopped, weakness improved and they began to gain weight favorably. At the end of the study there was a 7% average weight gain in all the subjects.¹⁹ There were no biochemical abnormalities noted on SMAC-24 throughout the study. Anemia induced by AZT showed improvement in all patients either previously on AZT or remaining on Retrovir throughout the study. Chest x-rays and EKG tracings remained within normal limits.

Discussion

It has been shown in previous studies that a deficiency in certain essential fatty acids might predispose to AIDS.²⁰⁻²⁶ It has also been noted that unsaturated free fatty acids inactivate animal enveloped viruses²⁷ of a balanced nutritional⁴ supplementation as described. Specific objectives of the study were to determine if this treatment caused remission, regression or halted the progression of this disorder as evidenced by clinical evaluation, laboratory testing, and subjective evaluation based upon questionnaire forms.

Based on this clinical pilot study, we conclude that nutritional supplementation is synergistic in lowering antigenemia and improving immune function in HIV seropositive patients at all

stages. Some studies show that diets high in arginine improve T4 function and laboratory counts.²⁶ Many AIDS patients are actually dying of starvation. Where wasting occurred, which is common in this disease, because of decreased food intake, malabsorption or metabolic alterations, by appropriate nourishment, significant improvement occurred in all our patients, even in those patients who would conventionally require TPN, without exposure to the risks of parenteral caloric intake. Most notably, diarrhea stopped and wasting reversed in all affected patients. A majority of them showed elevated triglycerides and decreased cholesterols at the outset of the study. Over half of the patients began normalizing their HDL, and cholesterol levels increased with a concurrent drop in P24 core antigens in those who were positive initially.

Because of continued improvement in a majority of patients at 180 days and beyond the conclusion of the studies, these nutritional pilot studies would indicate that this protocol might form the foundation of nutritional treatment in AIDS patients, as synergism is clearly seen in those patients taking other medications including AZT and Pentamidine. More specific and individualized studies with controls are now warranted as a large number of dietary products alter immune system function, and may be thought to possess pharmacologic nutritional effect, for example arginine, glutamine, omega 6 and omega 3 fatty acids, short-chain fatty acids, zinc, iron, and vitamins A, C, and E.²⁹ To this purpose a study should be initiated.

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A significant improvement in a clinical pilot study utilizing nutritional supplements, essential fatty acids and stabilized aloe vera juice

In 29 HIV SEROPOSITIVE ARC AND AIDS PATIENTS

August 16, 1989

By

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ABSTRACT

Although Nutritional Supplementation is certainly not a cure for AIDS it has been used for years for overall health improvement. It has been found that poor nutrition was one of the risk factors for progressing from HIV seropositive into ARC and into AIDS. It is felt that by improving the patient's nutritional status the possibility of progressing into full blown ARC or AIDS may be reduced or at least delayed, and the goal is to place the patient into long term remission. To accomplish this end, a powdered nutritional supplementation was furnished free of charge to all the patients, provided by True Health, Inc. along with essential fatty acid capsules and stabilized 100% pure Aloe Vera beverage.

It has been known in previous studies that a deficiency in certain essential fatty acids might predispose to AIDS. And it has also been noted that unsaturated free fatty acids inactivate animal enveloped viruses. Thus the hypothesis was that increasing the nutritional status of the patient while trying to inactivate the virus known to cause HIV infections might help to restore the immune system. Initially, 29 patients were selected, of whom 15 had a mean Walter Reed score consistent with a diagnosis of AIDS for a total of 51.7%. Twelve of 29 met the criteria for a diagnosis of lymphadenopathy syndrome or ARC or 41.3% and two of the 29 initial patients were asymptomatic, HIV seropositive or 6.8%. Modified Walter Reed scores on initial evaluation showed a median of 6.25 and a mean of 5.60 and at 90 days the evaluation period showed a median drop to 1.50 and a mean drop of 2.0. 100% of the patients improved on the Modified Walter Reed scores at 90 days. Karnofsky scores to evaluate quality of life assessment were done initially with a median of 80 and mean of 79.03 and at 90 days this evaluation of the median was 90 and the mean was 92.22. Twenty-seven of the 29 on the Karnofsky score had improved for a total of 93.1% and two of 29 had remained the same, for an average of 6.9%. T4 helper cell count was initially evaluated in all patients and in 15 of 29 or 51.7% the T4 helper lymphocytes increased. In 12 of 29 or 41.3% they decreased and in 2 of 29 or 6.9% they remained unchanged. Of greatest significance was the P24 core antigen assay in which at 90 days 4 out of 14 of those that were originally positive for the P24 core antigen had converted to nonreactive (not due to spontaneous deterioration of a failing immune system or end stage AIDS) for a total of 28.5%.

**A SIGNIFICANT IMPROVEMENT IN A CLINICAL PILOT STUDY
UTILIZING NUTRITIONAL SUPPLEMENTS, ESSENTIAL FATTY ACIDS
AND STABILIZED ALOE VERA JUICE
IN
29 HIV SEROPOSITIVE ARC AND AIDS PATIENTS
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INTRODUCTION

Acquired Immune Deficiency Syndrome or AIDS has claimed over 58,000 lives in the United States and it is expected to claim millions worldwide over the next few years. It is estimated that 1.~ million Americans are infected~ with the virus that causes AIDS but most of them do not know that they are infected. (AIDS causes special problems and concerns as to how AIDS is spread, how people can reduce the risk of contracting it and more principal is how the fight against AIDS is approached.) The fight against AIDS must have three fundamental goals. First - we must do all we can do to find a cure for AIDS, and a vaccine against the virus. Second - we must care for all the victims of the disease, this must include protecting them from injustice and persecution. And finally, we must take appropriate measures such as routine testing and effective education to protect the public health. Current therapies for AIDS are only palliative and directed only towards managing opportunistic infections. The possible beneficial effects of a balanced nutritional supplementation with the True Health capsules and Aloe Vera juice in HIV seropositive asymptomatic ARC and AIDS patients was going to be studied an open trial in 30 patients. A concurrent study is being conducted in which 10 patients are receiving only the powder and the capsules; another 20 patients are entering into a double blind placebo controlled study. Specific objectives of this study are to determine if this treatment causes remission or regression or helps to prevent the progression or spread of this disorder as evidenced by physical signs, laboratory measures and subjective reports.

The patients took the True Health capsules consisting of Cis-Linoleic acid or CLA, 280 mg.; Linolenic Acid-LA 80 mg.; Eicosapentaenoic Acid or EPA 45 mg.; Docosapentaenoic Acid or DPA 9 mg.; Docosahexaenoic Acid or DMA 30 mg. and d'alpha tocopherol -15 mg. per capsule for a total of 8 capsules daily, in a divided dose. They also took the True Health Nutritional Supplementation Powder, one level scoop 4 times a day in Aloe Vera juice which totaled 20 ounces of the beverage daily. Medications other than the studied nutrients were given by the patient's physician and monitored. Of the initial 51.7% of the patients with Walter Reed scores indicative of AIDS 5 of 29 or 24% presented status/post PCP. One out of the 29 presented with Kaposi's Sarcoma, cutaneously or 3%. Two of the 29 or 6% presented with miliary tuberculosis. One presented with lymphoma of the liver which was primary, in remission or 3%. Three of 29 presented with herpes for a total of 10%. One of the 29 patients presented with an AIDS Wasting Syndrome. One of 29 presented with CMV pneumonia or 3%. Three of 29 had concurrent Epstein-Barr virus infections or 10%. One had intermittent thrombocytopenic purpura with a splenectomy status/post or 1/29 for a total of 3%; and two of 29 presented with AZT induced anemias (off of the Retrovir) at the initiation of the study for a total of 6%.

Drugs that the patients were taking when they entered this study included Retrovir, (3 prior AZT treatment failures upon initiating the study); two entered the study at full dose Retrovir namely 200 mg. q.4.h. and one patient entered this study on Retrovir at one-half dose, 100 mg. q.4.h. Three of the 29 initial patients began and continued on Retrovir for a total of 10.34%. Six of the 29 patients were either on or had been on Retrovir at the initiation of this

study for a total of 20.6%. Seven of 29 patients had been on no drugs for a total of 24%. Two patients were on INH Ethambutol daily and Streptomycin and PZA 1500 mg. q.d. for a total of 6.8% of the patients. Four of the patients were on Nizoral for a total of 13.7%. Eight of the patient consumed alcohol on a regular basis for a total of 27.5%, and 4 patients smoked cigarettes greater than one pack per day for a total of 13.7%. 10.3% of the patient's had drug screens that produced the following divisions: 2 patients tested positive for marijuana and 1 heterosexual female patient tested positive for cocaine. Eleven of 29 patients entered the study and continued to receive aerosolized Pentamidine for a total of 37.9% of the patients. Four of the 29 patients received Zovirax capsules, 200 mg. t.i.d. for a total of 13.7% of the studied patients.

Risk behaviors of the patients upon entering the study were as follows: Of the 31 initial patients, two dropped from the study before completion of 90 days, not due to death but due to noncompliance. One of the patients was a heterosexual female with no other known risks. Her percentage was 3.4% of the study patients. One of the patients was a healthcare heterosexual worker who was an orthodontist or 3.4% of the study composition. Twenty-seven of the 29 patients were homosexual exclusively for a total of 93.1%. Celibate patients were 3 out of 27 of the homosexual patients for a total of 11.11%, those who practiced safe sex were 16 out of the 27 for a total of 59.25%. Monogamous homosexual relationships numbered eight out of the 27 for a total of 29.6%. Of the monogamous couples where the lover was positive and safe sex was practiced, five of the eight monogamous relationships were in that category for a total of 62.5% of those monogamous relationships. Where monogamy was practiced, the lover was positive, but unsafe sex was practiced equals one of the eight relationships for a total of 12.5%. Where monogamy was practiced, but the lover was negative, in a safe sex relationship that totaled two out of eight for a total of 25%.

No adverse effects attributable to the True Health essential fatty acid capsules were observed nor any side effects of the Nutritional Supplementation Powder nor of the Aloe Vera beverage. Most patients who were symptomatic reported that within three to five days their energy level improved, fever disappeared, night sweats stopped, cough decreased or stopped altogether, shortness of breath decreased, lymph nodes decreased in size, diarrhea stopped, weakness improved and the only measurable side effect of this particular study is weight gain which is a desired effect. There were no biochemical abnormalities noted on SMAC in this particular study. AZT induced anemias improved on this particular regimen. Chest x-rays remained normal at 90 days in all patients. No change in EKG from baseline were observed at 90 days. There was great improvement in all patients and a return of anergy patients to hypersensitivity skin tests at the end of 90 days. in 10 of 29 patients. The safety in this study was high because the nutritional supplements have been used for years for the general health and improvement with extremely limited to almost no toxic or allergic reactions. The need of this study was extreme as previously stated in the intent statement of initial purpose in that AIDS is an invariably fatal disease that is epidemic in its proportions, rapidly spreading as an increasing public health concern. There are no currently effective treatments available other than the combination of Retrovir and aerosolized Pentamidine as prophylactic and remedial measures. Not only did the patients improve clinically and functionally, but their Karnofsky scores improved in 93.1% of the patients. 100% of the modified Walter Reed scores improved at 90 days. 51.7% of the patient's T4 helper lymphocytes increased and 28.5%

reactive HIV P24 core antigen converted to negative at 90 days.

PROTOCOL DEVELOPMENT:

Method of Study in Detail

Purpose and hypothesis to be tested The possible beneficial effects of a balanced nutritional supplementation with True Health Capsules, True Health Aloe Vera beverage, and True Health Nutritional Supplementation Powder in HIV seropositive asymptomatic patients and ARC and AIDS was studied in an open trial of up to 30 patients. Specific objectives of this study were to determine if this treatment causes remission or regression or halts the progression and spread of this disorder as evidenced by physical science laboratory measures and subjective reports on the part of the patients.

Number of subjects and duration. This was a trial in 30 patients for an initial study period of 180 days. The program may be continued on an individual basis.

Mechanisms for subject selection or exclusion. In order to enter the study the patients had to meet the following criteria: Male or female outpatients, any age greater than 18 years old, each patient must satisfy the criteria for selection (HIV seropositive, asymptomatic; ARC; AIDS), each patient had to be capable of giving a valid informed consent to participate in this project and had to demonstrate culture of the AIDS virus from blood sample achieved by HIV antibody testing followed up by Western Blot, together with a T-4 T-8 Lymphocyte Ratio of less than 1, with no current exceptions. Each patient must have had a Karnofsky Quality of Life Assessment score of 20 or greater.

Each patient received gratis lab, physical, chest x-ray and EKG as outlined on a monthly review basis. Episodic interval care, however was at the patient's personal financial responsibility as were additional necessary tests not included in the study at prices approximating the cost to the investigator and his staff.

Since the purpose of this study was to determine under what conditions proper nutritional supplementation is a beneficial treatment for HIV related conditions, there were no current exclusion criteria to entering this study except for inability and unwillingness to comply with all facets of the study, inability to sign the informed consent, or hypersensitivity or anaphylactic type reaction to the food supplements, which would have predated immediate termination from this study. As the study proceeded, the patients continued in the program unless their T-4 count dropped below 12, the disease is too advanced or other treatment protocols were incompatible. No chemotherapeutic agents or radiation therapy could be undergone simultaneously and the patient remain an active participant in this particular study. There were no absolute contraindication except the nearly impossible life threatening adverse reaction to the nutritional supplements. Immunization to tetanus, influenza and pneumonia were be current and borne at the patient's expense if deficient. The patients were allowed to continue with all other medication regimens, including AZT.

Dosage Regimes and Duration. The patient entered into the study protocol were asked to

take the following nutritional supplements during the study: True Health Capsules, take 2 capsules 4 times a day; True Health Aloe Vera beverage, drink 5 ounces 4 times a day and True Health Nutritional Supplementation Powder, take 1 level scoop 4 times daily in water. Each patient received monthly supplies of the nutritional supplements. Medications other than the study nutrients were to be given by the patient's physician and or the study physician as the subject's condition appeared to require with accurate record keeping of dosaging and schedules and fully informing the other physician. Patients could withdraw from this study for any reason, any time. Specific criteria for stopping this study after initiating it were that the progression of the HIV seropositive asymptomatic, ARC or AIDS seemed to be unaffected by the nutritional supplementation or the disease process appeared to be hampering the clinical or laboratory evaluations in this particular individual. If so, the protocol was to be discontinued.

Clinical Evaluation:

Frequency and Character of Visits, Types of Data Collection.

- a. Frequency of clinical visits: Subjects were seen for thorough medical evaluation and laboratory studies initially and at 30 days, 60 days, 90 days and 180 days throughout the study.
- b. Clinical examination: Clinical examination was performed on the initial visit with subsequent complete physical examinations. Specifically, Modified Walter Reed Clinical Evaluation was calculated at monthly intervals. Lymphadenopathy was observed. Any T-4 count less than 400 was noted. Delayed skin hypersensitivity (DHS) to skin testing was evaluated. Thrush was noted. Any opportunistic infections were catalogued. Other individual clinical patient parameters included: persistent fatigue, night sweats, documented fever, persistent or episodic diarrhea at the time of entry into the study. The documentation also included their white blood cell count and it's differential, sedimentation rate, the lesions of the Kaposi's sarcoma both in number, shape, and location, and any other clinical or laboratory data furnished by the physician to the study researchers.
- c. Laboratory examination: Laboratory examinations performed at the initial evaluation were the Diagnostic Reflex Panel II, Sedimentation rate, RPR, T cell subsets, and P24 core antigen assay. At each subsequent monthly physician follow-up visit, laboratory examinations performed were a complete blood count with indices differentially, platelets, and sedimentation rate, SMAC-24 or it's equivalent, and a lymphocyte enumeration panel or a T4 T8 count in terms of ratio and absolute numbers. Other tests were performed on a case by case basis, depending on the clinical presentations and the physician's preferences at the time of admission to the study. All laboratory testing was performed by Damon Clinical Laboratories, Inc., 8300 Esters Blvd., Irving, Texas.
- d. Other studies: Vital signs including blood pressure, temperature, pulse, and respirations, as well as, weight were recorded at monthly intervals during the course of this study. Extensions: Extensions of additional six month to twelve month extension periods for the supplement and systematic evaluation were to be conducted once informed consent is given and on a less frequent basis, once benefit

has been derived from this particular study, but only through the agreement of both the investigator and the patient.

Study subjects would be terminated from the study if any of the following occurred: Serious anaphylactic or adverse reaction to the nutritional supplements, lack of efficacious effect in the patient, the patient's personal preference and request to withdraw from the study, protocol violations on the part of the patient or if the study itself was to be terminated.

CLINICAL RESULTS:

NUTRITIONAL SUPPLEMENTATION STUDY #1

COLLECTED DATA

DRUGS THE STUDY PARTICIPANTS WERE TAKING WHEN THEY ENTERED THE STUDY

PATIENT

- | | | |
|-----|---------------------------------------|---|
| 1. | OTHER DRUGS | INH/Ethambutol Daily (Miliary TB)
Streptomycin, 1 gm 2 x wk.
PZA, 1500 mg. Q.D. |
| 2. | AZT
PENTAMIDINE
ZOVIRAX | 200 mg. Q 4 hours
300 MG. Q mo.
200 mg. TID (Chronic EBV) |
| 3. | PENTAMIDINE
OTHER DRUGS | 150 mg. Q 2 weeks
ETOH/Cigarettes |
| 4. | OTHER DRUGS | Accutane
ETOH/Cigarettes |
| 5. | PENTAMIDINE
ZOVIRAX
OTHER DRUGS | 300 mg. Q mo.
200 mg. TID (EBV)
Completed CHOP/Liver chemotherapy for
Primary Lymphoma |
| 6. | NONE | |
| 7. | ZOVIRAX | 200 mg. 5 caps. Q 8 hr. |
| 8. | DROPPED FROM STUDY | |
| 9. | NONE | |
| 10. | NONE | |
| 11. | OTHER DRUGS | ETOH |
| 12. | PENTAMIDINE
OTHER DRUGS | 300 mg. Q mo.
INH |
| 13. | AZT | AZT induced anemia (d/c'd on start in study) |
| 14. | PENTAMIDINE
OTHER DRUGS | 300 mg. Q mo.
Niazoral 200 mg. Q D (Onchomycosis) |
| 15. | PENTAMIDINE | 300 mg. Q mo.
(AIDS dementia) |

16.	ZOVIRAX	200 mg. (EBV)
17.	NONE	
18.	OTHER DRUGS	Isoprinosine 500 mg., 2 p.o., TID
19.	NONE	
20.	AZT	200 mg. Q 4 hr
	PENTAMIDINE	300 mg. Q mo.
	OTHER DRUGS	Mycelex ETOH
21.	AZT	None. AZT failure
	PENTAMIDINE	300 mg. Q mo.
22.	DROPPED FROM STUDY	(Had KS) P24 core antigen dropping from 9 to 4
23.	OTHER DRUGS	ETOH/Cigarettes
24.	AZT	AZT (Aug - Oct 88), dc'd violent reaction three months into the study
	PENTAMIDINE	300 mg. Q mo.
25.	OTHER DRUGS	ETOH/Cigarettes + for Marijuana
26.	PENTAMIDINE	150 mg. Q 2 wk. S/P PCP
	OTHER DRUGS	Nizoral 200 mg. QD ETOH + for Marijuana
27.	AZT	100 mg. Q 4 hr.
	PENTAMIDINE	150 mg. Q 2 wks.
	ZOVIRAX	200 mg. Q 8 hr.
28.	OTHER DRUGS	Nizoral 200 mg. ETOH/Cigarettes
29.	OTHER DRUGS	ETOH/Cigarettes
30.	NONE	
31.	OTHER DRUGS	+ for Cocaine on Drug Screen

CLINICAL RESULTS:

NUTRITIONAL SUPPLEMENTATION STUDY #1

COLLECTED DATA

OPPORTUNISTIC INFECTIONS, CANCER, RPR POSITIVE AND OTHER
CONDITIONS

PRESENT INITIALLY OR DURING THE TREATMENT OF THE STUDY
PARTICIPANTS

PATIENT #

1. OPPORTUNISTIC INFECTIONS Miliary TB
2. OPPORTUNISTIC INFECTIONS S/P PCP
OTHER CONDITIONS EBV
3. NONE
4. NONE
5. CANCER Primary Liver Lymphoma
OTHER CONDITIONS EBV
6. NONE
7. OTHER CONDITIONS Chronic herpetic proctitis
8. DROPPED FROM STUDY
9. NONE
10. NONE
11. NONE
12. OPPORTUNISTIC INFECTIONS Miliary TB (Rx'd)
CANCER Kaposi's Sarcoma, 7-24-89, Cutaneous
13. OPPORTUNISTIC INFECTIONS AIDS Wasting Syndrome
OTHER CONDITIONS Anemia Secondary to AZT
14. NONE
15. OTHER CONDITIONS Herpetic Zoster/AIDS Dementia
16. OTHER CONDITIONS EBV
17. OTHER CONDITIONS AZT induced Anemia
18. NONE
19. NONE
20. OTHER CONDITIONS Venereal Warts
21. OPPORTUNISTIC INFECTIONS S/P PCP
OTHER CONDITIONS AZT induced Anemia
22. DROPPED FROM STUDY
CANCER Kaposi's Sarcoma, widespread, cutaneous
23. NONE
24. OPPORTUNISTIC INFECTIONS S/P PCP
25. NONE
26. OPPORTUNISTIC INFECTIONS S/P PCP
27. OPPORTUNISTIC INFECTIONS S/P PCP
OTHER CONDITIONS Anal Condyloma
Herpetic Proctitis
CMV
28. OTHER CONDITIONS ITP, S/P SPLENECTOMY NOV '85
29. NONE
30. NONE
31. NONE

CLINICAL RESULTS:

NUTRITIONAL SUPPLEMENTATION STUDY #1

COLLECTED DATA

SEXUAL PRACTICES OF STUDY PARTICIPANTS (HOMOSEXUAL, BISEXUAL, HETEROSEXUAL, HEALTHCARE WORKER, IV DRUG USER, TRANSFUSION)

PATIENT #1

1.	HOMOSEXUAL	Receptive, Anal
2.	HOMOSEXUAL	Safe sex, Receptive, Active
3.	HOMOSEXUAL	Safe sex
4.	HOMOSEXUAL	Oral sex
5.	HOMOSEXUAL	Safe sex, Monogamous, - Lover
6.	HOMOSEXUAL	Safe sex
	HEALTHCARE WORKER	Orthodontist
7.	HOMOSEXUAL	Receptive
	HEALTHCARE WORKER	Physician
8.	DROPPED FROM STUDY	
9.	HOMOSEXUAL	Safe sex
10.	HOMOSEXUAL	Safe sex
11.	HOMOSEXUAL	Safe sex
12.	HOMOSEXUAL	Safe sex, Monogamous
13.	HOMOSEXUAL	Safe sex, Monogamous
14.	HOMOSEXUAL	Active
15.	HOMOSEXUAL	Receptive, Anal
16.	HOMOSEXUAL	Receptive, Active
17.	HOMOSEXUAL	Safe sex, Active, Anal
18.	HOMOSEXUAL	Safe sex, Oral, Monogamous, + Lover
19.	HOMOSEXUAL	Safe sex, Multiple
20.	HOMOSEXUAL	Non-Monogamous, + Lover
21.	HOMOSEXUAL	Celibate
22.	DROPPED FROM STUDY	
23.	HOMOSEXUAL	Safe sex, Monogamous, - Lover
24.	HOMOSEXUAL	Safe sex, Monogamous, + Lover (AIDS)
25.	HOMOSEXUAL	Safe sex, Active, Anal, Oral, Multiple
26.	HOMOSEXUAL	Safe sex, Anal, Oral
27.	HOMOSEXUAL	Celibate
28.	HOMOSEXUAL	Unsafe sex - '84 Safe sex - now

- | | |
|------------------|--|
| 29. HOMOSEXUAL | Anal, Rimming, Oral - until '84
Celibate 2 1/2 yrs (always anal receptive before) |
| 30. HOMOSEXUAL | Safe sex, Multiple |
| 31. HETEROSEXUAL | Safe sex |

CLINICAL RESULTS:

NUTRITIONAL SUPPLEMENTATION STUDY #1

STATISTICAL INFORMATION

HEALTH STATUS OF PATIENTS ENTERING THE STUDY

MODIFIED WALTER REED EVALUATION

INITIAL EVALUATION

06.8%	ASYMPTOMATIC	(02/29)
41.3%	ARC	(12/29)
51.7%	AIDS	(15/29)

90 DAY EVALUATION

58.6%	ASYMPTOMATIC	(17/29)
41.3%	ARC	(12/29)
00.0%	AIDS	(00/29)
100%	OVERALL IMPROVEMENT AT 90 DAYS	

KARNOFSKY SCORES

INITIAL EVALUATION

00%	SCORE OF <50	NONE
13.8%	SCORE OF 50	(04/29)
06.9%	SCORE OF 60	(02/29)
06.9%	SCORE OF 70	(02/29)
24.1%	SCORE OF 80	(07/29)
37.9%	SCORE OF 90	(11/29)
06.9%	SCORE OF 100	(02/29)

90 DAY EVALUATION

00%	SCORE OF <50	NONE
00%	SCORE OF 50	NONE
00%	SCORE OF 60	NONE
03.4%	SCORE OF 70	(01/29)
13.8%	SCORE OF 80	(04/29)
37.9%	SCORE OF 90	(11/29)

44.8% SCORE OF 100 (13/29)
93.1% HAD IMPROVED SCORES AT 90 DAYS (27/29)
06.9% HAD THE SAME SCORES AFTER 90 DAYS (02/29)

P24 CORE ANTIGEN

INITIAL EVALUATION

17 OF THE PATIENTS WERE SERONEGATIVE

14 OF THE PATIENTS WERE SEROPOSITIVE

90 DAY EVALUATION

28.5% OF THE PATIENTS WHO WERE INITIALLY SEROPOSITIVE BECAME SERONEGATIVE AT 90 DAYS (4 OF THE 14 WHO WERE INITIALLY POSITIVE)

T4 HELPER LYMPHOCYTES (NORMAL 518-1605)

INITIAL EVALUATION

79.3% 23 PATIENTS WITH ABNORMAL T CELL COUNTS

20.7% 06 PATIENTS WITH NORMAL T CELL COUNTS

90 DAY EVALUATION

72.4% 21 PATIENTS WITH ABNORMAL T CELL COUNTS

27.6% 08 PATIENTS WITH NORMAL T CELL COUNTS

51.7% INCREASED (15/29)

41.3% DECREASED (12/29)

06.9% UNCHANGED (02/29)

06.9% BECAME NORMAL AT 90 DAYS (02/29)

DELAYED HYPERSENSITIVITY TESTING

34.4% FULL DELAYED HYPERSENSITIVITY AT INITIAL EVALUATION AND 90 DAYS (10/29)

20.7% PARTIAL RESTORATION OF DELAYED HYPERSENSITIVITY AT THE END OF 90 DAYS (6/29)

10.3% ANERGIC AT THE BEGINNING AND REMAINED ANERGIC AT THE END OF 90 DAYS (03/29)

34.4% OF 13 HAVING NO REACTION AT THE BEGINNING, 10 HAD FULL RESTORATION OF REACTIVITY AT THE END (10/29)

CLINICAL RESULTS:

NUTRITIONAL SUPPLEMENTATION STUDY #1

STATISTICAL INFORMATION

DRUGS THE STUDY PARTICIPANTS WERE TAKING WHEN THEY ENTERED

THE STUDY

24.1%	<u>NO DRUGS USED OR PRESCRIBED</u>	
20.6%	<u>AZT</u>	CONTACT WITH AZT EITHER TAKING IT AT THE TIME THEY ENTERED THE STUDY OR TOOK IT AT A PRIOR TIME
	10.34% (3/29)	2 PTS. AT FULL DOSE 1 PT. AT HALF DOSE
37.9%	<u>PENTAMIDINE</u>	(11/29)
13.7%	<u>ZOVIRAX</u>	(4/29)
51.7%	<u>OTHER DRUGS</u>	(15/29)
	06.8%	(2/29) 2 INH (TB) One taking Streptomycin, INH and PZA
	13.79%	(4/29) 4 NIZORAL 200 mg. QD (Onchomycosis)
	03.4%	(1/29) 1 CHEMOTHERAPY - CHOP (Primary Lymphoma)
	03.4%	(1/29) 1 ISOPRINOSINE
	03.4%	(1/29) 1 MYCELEX
	10.3%	(3/29) 2 PTS. MARIJUANA
		ILLICIT 1 PT. COCAINE
	13.7%	(4/29) CIGARETTES
	27.5%	(8/29) ETOH
27.6%	<u>OPPORTUNISTIC INFECTIONS</u>	(8/29)
	03%	(1/29) AIDS Wasting Syndrome
	04%	(5/29) PCP
06%	<u>CANCER</u>	(2/29)
	03%	(1/29) Kaposi's Sarcoma
	03%	(1/29) Lymphoma of Liver - Primary
37.9%	<u>OTHER CONDITIONS</u>	(11/29)
	03%	(1/29) ITP - Splenectomy
	03%	(1/29) CMV Pneumonia
	03%	(1/29) AIDS Dementia
	03%	(1/29) Anal Condyloma
	07%	(2/29) Anemia secondary to AZT
	06%	(2/29) AZT - induced Anemia
	06%	(2/29) Tuberculosis
	10%	(3/29) Herpes
	10%	(3/29) EBV

SEXUAL PRACTICES OF STUDY PARTICIPANTS (HOMOSEXUAL, BISEXUAL, HETEROSEXUAL, HEALTHCARE WORKER, IV DRUG USER, TRANSFUSION)

OVERALL STUDY GROUP

96.6%	MALE	(28/29)		
03.4%	FEMALE	(01/29)		
93.1%	HOMOSEXUAL	(27/29)	3.4%	HEALTHCARE (1/29)
06.9%	HETEROSEXUAL	(2/29)	3.4%	HEALTHCARE (1/29)
			3.4%	FEMALE (1/29)

HOMOSEXUAL

HOMOSEXUAL

11.11% CELIBATE (3/27)

OF THOSE WHO ARE NOT CELIBATE

59.25%	PRACTICE SAFE SEX	
29.6%	MONOGAMOUS	(8/27)
62.5%	MONOGAMY/LOVER +, SAFE SEX	(5/27)
12.5%	MONOGAMY/LOVER +, UNSAFE SEX	(1/27)
25.0%	MONOGAMY/LOVER -, SAFE SEX	(2/27)
0%	MONOGAMY/LOVER -, UNSAFE SEX	(0/27)
7.4%	MULTIPLE PARTNERS	(2/27)

HETEROSEXUAL

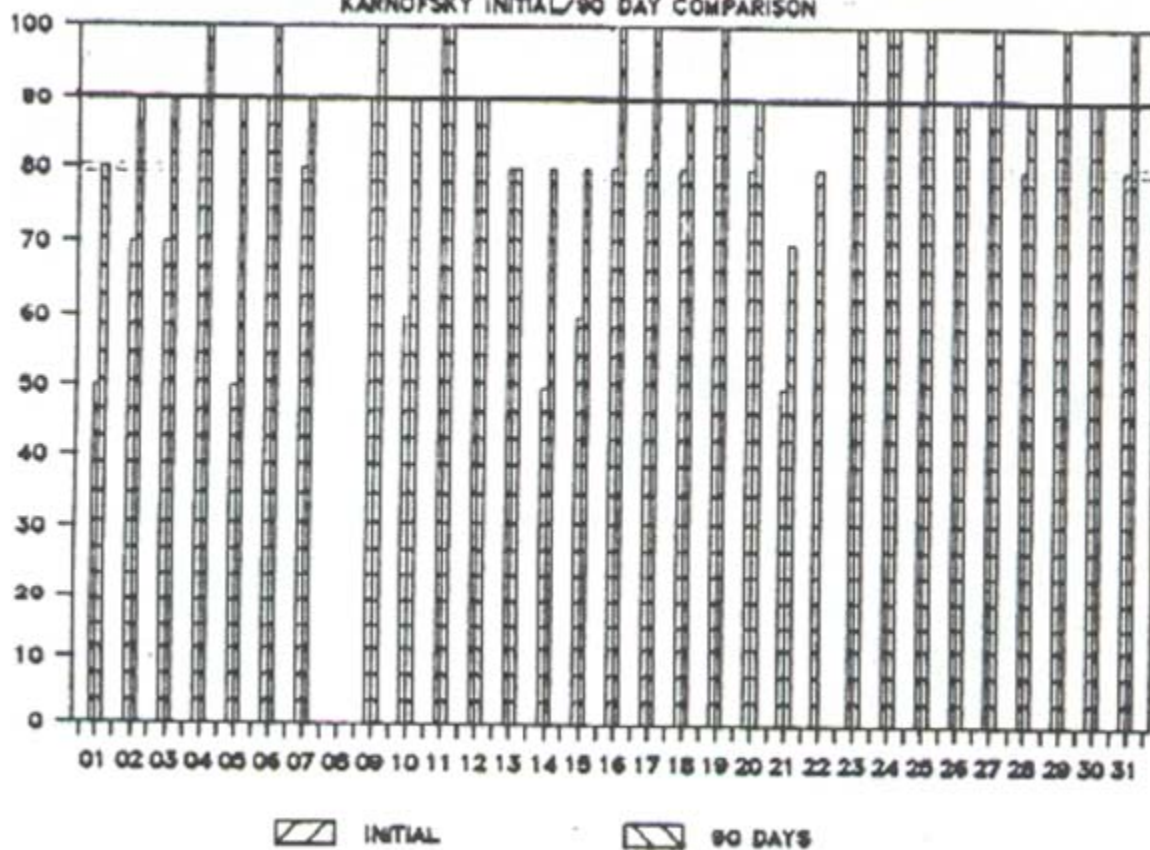
100%	HETEROSEXUAL	Safe sex	(2/2)
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BISEXUAL

0%	BISEXUAL		(0/0)
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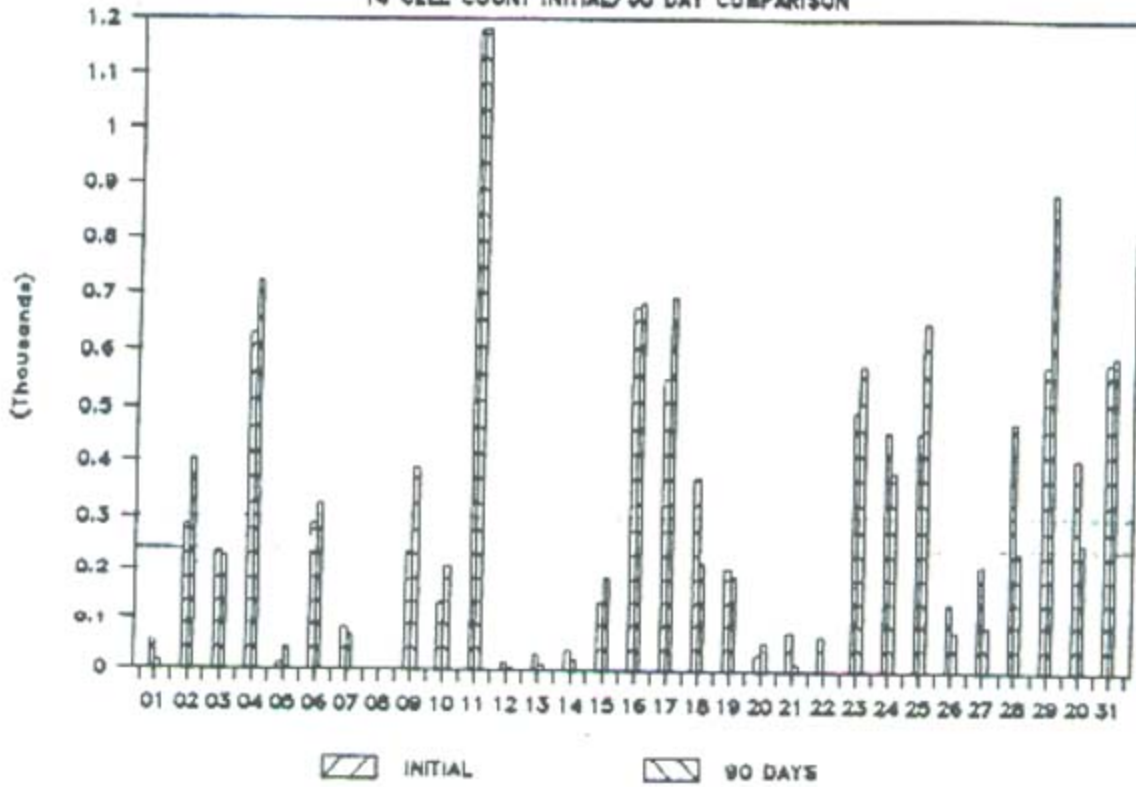
NUTRITIONAL SUPPLEMENTATION STUDY #1

KARNOFSKY INITIAL/90 DAY COMPARISON



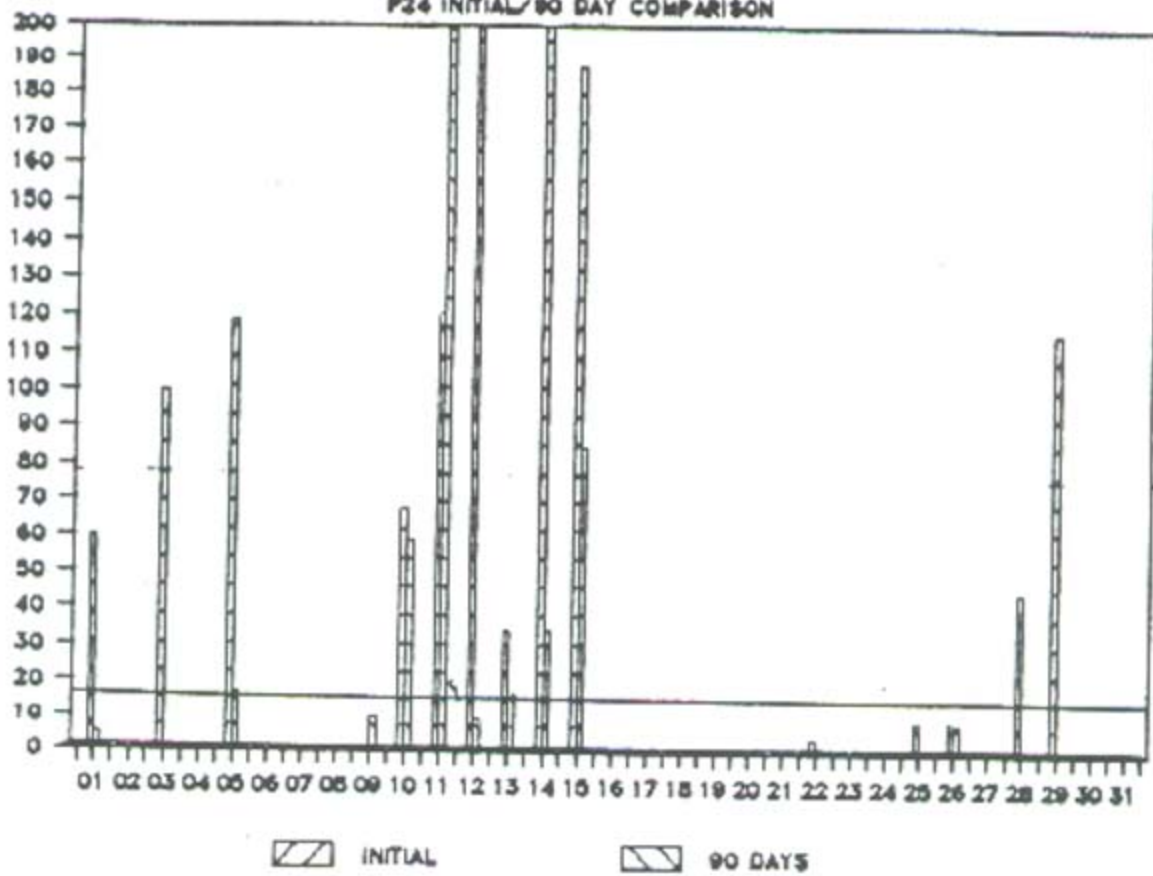
NUTRITIONAL SUPPLEMENTATION STUDY #1

T4 CELL COUNT INITIAL/90 DAY COMPARISON



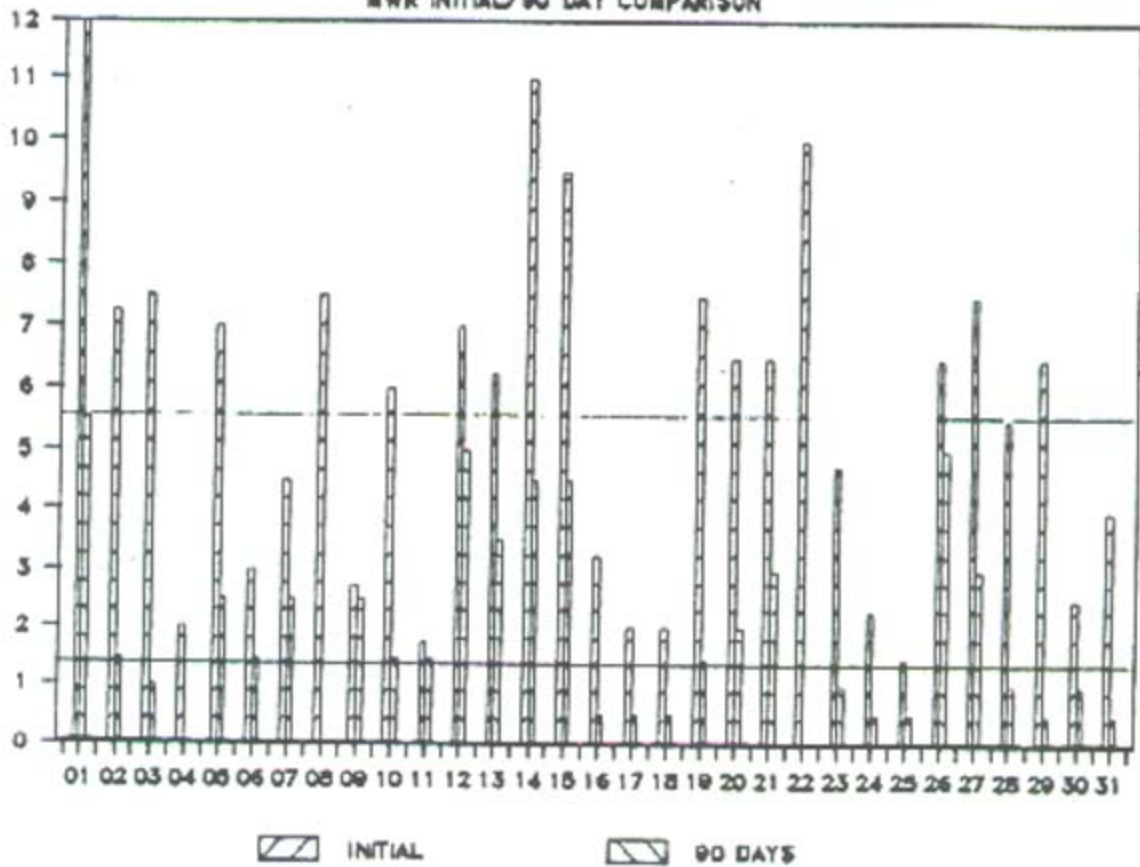
NUTRITIONAL SUPPLEMENTATION STUDY #1

P24 INITIAL/90 DAY COMPARISON



NUTRITIONAL SUPPLEMENTATION STUDY #1

MWR INITIAL/90 DAY COMPARISON



Graph for Karnofsky Scores

	s01	s02	s03	s04	s05	s06	s07	s08	s09	s10	s11	s12	s13	s14	s15	s16	s17
Initial	50	70	70	90	50	90	80		90	60	100	90	80	50	60	80	80
90 Days	80	90	90	100	90	100	90		100	90	100	90	80	80	80	100	100
180 Days																	

Graph for T-4 Cell Count

	s01	s02	s03	s04	s05	s06	s07	s08	s09	s10	s11	s12	s13	s14	s15	s16	s17
Initial	55	285	234	629	39	261	84		236	178	1378	17	33	41	138	677	554
30 Days	37	460	239	715	33	308	58		365	158	656	17	17	44	52	894	645
60 Days	17	156	261	656	36	363	74		749	305	157	9	13	54	81	762	640

Days
 90
 Days 17 406 227 724 43 323 70 390 211 1184 4 9 24 186 687 696
 120
 Days
 150
 Days
 180
 Days

Graph for Karnofsky Scores Con't

	s18	s19	s20	s21	s22	s23	s24	s25	s26	s27	s28	s29	s30	s31
Initial	80	90	80	50	80	90	100	90	90	90	80	90	90	80
90 Days	90	100	90	70		100	100	100	90	100	90	100	90	100
180 Days														

Graph for T-4 Cell Count Con't

	s18	s19	s20	s21	s22	s23	s24	s25	s26	s27	s28	s29	s30	s31
Initial	375	206	35	53	71	500	464	460	138	213	480	580	411	585
30 Days	359	260	23	35	52	616	333	432	96	176	218	1083	664	462
60 Days	541	245	30	42		501	428	432	96	191	239	1001	458	462
90 Days	215	191	53	17		578	384	651	80	89	239	890	256	595
120 Days														
150 Days														
180 Days														

Graph for TMWR Scores

s01 s02 s03 s04 s05 s06 s07 s08 s09 s10 s11 s12 s13 s14 s15 s16 s17

Days
150
Days
180
Days

Graph for P24 Con't

	s18	s19	s20	s21	s22	s23	s24	s25	s26	s27	s28	s29	s30	s31
Initial	0	0	0	0	4	0	0	9	0	0	45	73	0	0
30 Days	0	0	0	0	9	0	0	12	6	0	39	4	0	0
60 Days	0	0	0	0		0	0	12	6	0	0	5	0	0
90 Days	0	0	0	0		0	0	19	8	0	0	0	0	0
120 Days														
150 Days														
180 Days														

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CONCLUSIONS:

A controlled double blind placebo study is needed to determine the effectiveness of this drug and is currently underway in a group of 30 more patients. We conclude that nutritional supplementation is synergistic in lowering antigenemia and improving immune function in HIV seropositive patients at all stages and needs expanded testing on a global basis. We anticipate continued improvement in a majority of patients at 180 days, noting that this nutritional pilot study may form the foundation of treatment in AIDS patients as synergism is c¹early seen in those patients taking other medications including AZT and Pentamidine. Further, we conclude that this regimen of nutritional supplementation is a cost effective, active ingredient in halting the progression of the AIDS virus, boosting the immune system while decreasing the P24 core antigen activity and improving the overall quality of patient's lives.

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