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Metabolic Syndrome and Functional Food

This study has been completed.

Sponsor:
Universidad Autonoma de Nuevo Leon

Information provided by (Responsible Party):
Lilia Csrdenas-Ibarra, Universidad Autonoma de Nuevo Leon

ClinicalTrials.gov Identifier:
NCT00916175

First received: June 8, 2009
Last updated: June 28, 2012
Last verified: July 2009
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	June 8, 2009
Last Updated Date	June 28, 2012
Start Date ICMJE	October 2008
Primary Completion Date	December 2008 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: June 8, 2009)	Reduction of elevated blood sugar (HbA1c) by Immunoturbidimetric test (One-HbA1c FS) via Star-Dust MC15; both from Diagnostic systems international (DiaSys); its coefficient of variation was 1.6%. [Time Frame: baseline, and at the end of each of 2 treatment periods of 4 weeks] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT00916175 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE (submitted: June 8, 2009)	• Significant changes on hematic biometry and liver function test and evaluation of any symptoms reported. [Time Frame: baseline, and after four weeks of treatment or sooner if needed] [Designated as safety issue: Yes] • Tolerance assessed by weekly inquiry of effort needed to take the product, wellbeing, energy, gastrointestinal complains, control of appetite and general complaints. [Time Frame: after each week taking the product] [Designated as safety issue: Yes]
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Metabolic Syndrome and Functional Food
Official Title ICMJE	Randomized Double Blind Factorial Assay, **Aloe Vera** (AV) And/Or Cnidoscolus Chayamansa (CC) Versus Placebo, Reduction Of High Blood Glucose In Women With Metabolic Syndrome
Brief Summary	High blood sugar and adiposity are part of Metabolic syndrome (about 24% of adults harbor it). The main approach, weight reduction, is often unattainable. **Aloe Vera** (barbadensis) (AV) and cnidoscolus chayamansa (McVaugh)(CC) are two vegetables that seem to have an effect on blood glucose and body weight. The study aims to determine if the intake of **aloe** gel and/or Chaya infusion can reduce high blood sugar in adult women with pre-diabetes (Metabolic Syndrome). Methods: A Factorial assay, double blind, cross-over-controlled with random assignment, to four treatments: AV and CC, AV and Placebo 1, Placebo 2 and CC, and Placebo 1 and Placebo 2, at the outpatient clinic of the university Hospital and a community clinic. Two treatment periods of 4 weeks intermediated by one week for wash-out.
Detailed Description	*Not Provided*
Study Type ICMJE	Interventional
Study Phase	Phase 2 Phase 3
Study Design ICMJE	Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Crossover Assignment Masking: Double Blind (Subject, Caregiver, Outcomes Assessor) Primary Purpose: Treatment
Condition ICMJE	Metabolic Syndrome
Intervention ICMJE	• Dietary Supplement: placebo1 and placebo2 30ml liquid resembling **aloe vera** juice plus 200ml liquid resembling chayamansa infusion • Dietary Supplement: Placebo 2 and CC Cnidoscolus Chayamansa infusion Other Name: te of chaya • Dietary Supplement: **Aloe Vera** and placebo 1 **aloe vera** juice and placebo 1 Other Name: Sabila • Dietary Supplement: **Aloe Vera** and Cnidoscolus Chayamansa **aloe vera** juice plus Cnidoscolus chayamansa infusion Other Names: ◦ Sabila ◦ te of chaya
Study Arm (s)	• Placebo Comparator: Placebo 2 & Placebo 1 Food product with 30ml placebo 2 (placebo **aloe vera** gel/juice) and 200ml placebo2 (placebo CC infusion): ◦ first period (4 weeks) food product (one 230ml lemon gelatin before breakfast) plus 1500 kilocalories diet ◦ second period (4 weeks) food product (two 230ml lemon gelatin one before breakfast and other after supper) plus 1500 kilocalories diet Intervention: Dietary Supplement: placebo1 and placebo2 • Experimental: Placebo 2 & CC Product containing 30ml placebo 2 (mimics **aloe vera** gel/juice) and 200ml of CC infusion: ◦ first period (4 weeks) food product (one 230ml lemon gelatin before breakfast) plus 1500

	kilocalories diet ◦ second period (4 weeks) food product (two 230ml lemon gelatin one before breakfast and other after supper) plus 1500 kilocalories diet Intervention: Dietary Supplement: Placebo 2 and CC • Experimental: AV & Placebo 1 Food product containing 30ml **aloe vera** gel/juice and 200ml placebo 1 (placebo CC infusion): ◦ first period (4 weeks) food product (one 230ml lemon gelatin before breakfast) plus 1500 kilocalories diet ◦ second period (4 weeks) food product (two 230ml lemon gelatin one before breakfast and other after supper) plus 1500 kilocalories diet Intervention: Dietary Supplement: **Aloe Vera** and placebo 1 • Experimental: AV and CC Food product containing 30ml **aloe vera** gel/juice and 200ml CC infusion: ◦ first period (4 weeks) food product(one 230ml lemon gelatin before breakfast) plus 1500 kilocalories diet ◦ second period (4 weeks) food product (two 230ml lemon gelatin one before breakfast and other after supper)plus 1500 kilocalories diet Intervention: Dietary Supplement: **Aloe Vera** and Cnidoscolus Chayamansa
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Completed
Enrollment ICMJE	125
Completion Date	February 2009
Primary Completion Date	December 2008 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion criteria: • Adult women living in Monterrey, Mexico with at least three of the following: ◦ waist line equal or larger than 88 cm ◦ fasting blood sugar between 100-140 mg/dL without symptoms or known glucose intolerance or diabetes treated only with diet ◦ known high blood pressure or 2/3 readings systolic > 130 mmHg, diastolic > 85 ◦ HLD < 50 mg/dL or triglycerides > 150 mg/dL Exclusion Criteria: • Pregnancy or nursing • On anti-diabetic agents • Diabetic symptoms or advanced DM complications • Severe behavioral problems
Gender	Female
Ages	20 Years to 70 Years
Accepts Healthy Volunteers	No

Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Location Countries ICMJE	Mexico

Administrative Information

NCT Number ICMJE	NCT00916175
Other Study ID Numbers ICMJE	EN_LC_P134
Has Data Monitoring Committee	Yes
Responsible Party	Lilia Csrdenas-Ibarra, Universidad Autonoma de Nuevo Leon
Study Sponsor ICMJE	Universidad Autonoma de Nuevo Leon
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	Principal Investigator: Lilia Cardenas-Ibarra, MD — Endocrinology, University Hospital, Universidad Autonoma de Nuevo Leon Study Chair: Jesus Zacarias Villarreal-Perez, MD — Endocrinology, University Hospital, Universidad Autonoma de Nuevo Leon
Information Provided By	Universidad Autonoma de Nuevo Leon
Verification Date	July 2009

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**