Effect of Aloe Vera in the Inflammation of Patients With Mild Ulcerative Colitis (AVIUC)

The recruitment status of this study is unknown because the information has not been verified recently.

Verified January 2013 by National Institute of Medical Sciences and Nutrition, Salvador Zubiran.
Recruitment status was Recruiting

Sponsor:
National Institute of Medical Sciences and Nutrition, Salvador Zubiran

Information provided by (Responsible Party):
Jesús Kazuo Yamamoto Furusho, National Institute of Medical Sciences and Nutrition, Salvador Zubiran

ClinicalTrials.gov Identifier: NCT01783119
First received: January 31, 2013
Last updated: February 1, 2013
Last verified: January 2013

Purpose

The Ulcerative Colitis (UC) belongs to the group of diseases called Inflammatory Bowel Disease (IBD) which is characterized by a chronic ulceration of the colon. The conventional treatment can have adverse effects and does not guarantee effectiveness in some patients requiring aggressive therapy using adjuvant therapy. Aloe vera has been shown to have a beneficial effect in different diseases and has an anti-inflammatory effect in UC patients. Objective: Measuring the effect of the consumption of 200 ml of aloe vera gel daily for a period of three months, in the degree of inflammation in patients with mild UC based on Mayo scale and quantification of IL-6 in the colonic mucosa.

- **Condition**: Ulcerative Colitis
- **Intervention**: Dietary Supplement: Aloe Barbadensis Miller
  Dietary Supplement: placebo water
- **Phase**: Phase 0

Study Type: Interventional
Study Design: Allocation: Randomized
  Endpoint Classification: Safety/Efficacy Study
  Intervention Model: Parallel Assignment
  Masking: Double Blind (Subject, Investigator)
  Primary Purpose: Treatment

Official Title: Effect of Aloe Vera in the Inflammation of Patients With Mild Ulcerative Colitis

Resource links provided by NLM:

- Genetics Home Reference related topics: ulcerative colitis
- MedlinePlus related topics: Ulcerative Colitis
- Drug Information available for: Aloe vera
- U.S. FDA Resources

Further study details as provided by National Institute of Medical Sciences and Nutrition, Salvador Zubiran:

Primary Outcome Measures:
- Full Mayo Score [ Time Frame: 3 months ] [ Designated as safety issue: Yes ]
- Interleukine - 6 [ Time Frame: 3 months ] [ Designated as safety issue: Yes ]
  Quantification in mucosal Biopsy
Estimated Enrollment: 60
Study Start Date: August 2012
Estimated Study Completion Date: December 2014
Estimated Primary Completion Date: December 2013 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Experimental: Aloe Vera</td>
<td>Dietary Supplement: Aloe Barbadensis Miller</td>
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<tr>
<td>Consume 200 ml of aloe vera gel per day over a period of three months</td>
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<tr>
<td>Placebo Comparator: water</td>
<td>Dietary Supplement: placebo water</td>
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<tr>
<td>Consume 200 ml of placebo per day over a period of three months</td>
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**Eligibility**

**Ages Eligible for Study:** 18 Years to 59 Years
**Genders Eligible for Study:** Both
**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- Patients with confirmed diagnosis by histopathology of Ulcerative Colitis with mild activity level clinical, Endoscopic and histological.
- Extent of disease: pancolitis, ulcerative proctitis and left.
- Being treated with 5 - aminosalicylates (5-ASA).
- Belonging to the National Institute of Medical Sciences and Nutrition "Salvador Zubirán".
- Signed informed consent.

**Exclusion Criteria:**
- Autoimmune diseases (lupus, HIV, cancer and any hepatitis).
- Another type of colitis (indeterminate, infectious drug and Crohn's Disease.
- Previous total colectomy.
- Body mass index less than 19.9 kg/m2 or greater than 40 kg/m2.
- Patients in remission histology, clinical and endoscopic.
- Under treatment with steroids, azathioprine, diuretics and anticoagulants.
- Use Aloe Vera or some natural therapy.

**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01783119

**Contacts**

Contact: Jesús K. Yamamoto-Furusho, PhD, MD +5554870900 ext 2710 kazuofurusho@hotmail.com

**Locations**

Mexico

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**Sponsors and Collaborators**

National Institute of Medical Sciences and Nutrition, Salvador Zubiran

**Investigators**

Study Chair: Jesús K Yamamoto-Furusho, MD, PhD INCNMSZ
Publications:


Responsible Party: Jesús Kazuo Yamamoto Furusho, MD PhD, National Institute of Medical Sciences and Nutrition, Salvador Zubiran
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Health Authority: México: Ethics Committee

Keywords provided by National Institute of Medical Sciences and Nutrition, Salvador Zubiran:
Ulcerative Colitis
Aloe Vera

Additional relevant MeSH terms:
Colitis: Gastroenteritis
Colitis, Ulcerative: Gastrointestinal Diseases
Ulcer: Inflammatory Bowel Diseases
Colonic Diseases: Intestinal Diseases
Digestive System Diseases: Pathologic Processes

ClinicalTrials.gov processed this record on March 26, 2015