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Healia Clinical Trials Information Database

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Effect of Yogurt Supplementation on Psychometric Test Performance in Cirrhotic Patients With Minimal Hepatic Encephalopathy. A Prospective Pilot Trial.

The purpose of this study is to determine whether a special yogurt can improve performance on certain tests of intelligence and decrease liver [inflammation](#) in patients with cirrhosis.

Status: Completed (N/A). Started on November 1st, 2005. Ended on April 1st, 2007.

Description

Enrollment: 30 subjects

Introduction: [Cirrhosis](#) is one of the leading causes of death in the United States. Minimal [hepatic encephalopathy](#) (MHE) is a significant complication of cirrhosis, which is often not treated because of perceived subclinical nature of this condition and the adverse effects and expense of available medications such as [lactulose](#) or [rifaximin](#). There is evidence that small intestinal bacterial overgrowth can contribute to the development of MHE and cirrhosis in murine and human studies. [Probiotics](#) are live [bacteria](#) that can modify the indigenous intestinal bacterial flora and have been recently used in the treatment of hepatic encephalopathy in patients with cirrhosis.

Study Type: Interventional

Study Design:

- Treatment
- Randomized
- Open Label
- Placebo Control
- Parallel Assignment
- Efficacy Study

Our aim is to evaluate the effect of probiotic supplementation via yogurt on liver function and [inflammatory](#) markers of bacterial [translocation](#) and psychometric test performance in cirrhotic patients with MHE in a prospective pilot trial.

Conditions:

- [Cirrhosis](#)
- [Minimal Hepatic Encephalopathy](#)

Methods: 30 patients with MHE 2:1 i.e. 20 will be randomized into supplementation with yogurt to be taken 6 ounces twice a day for 60 days and 10 patients will be followed up without yogurt supplementation. All patients will undergo liver function tests, basic metabolic panel, [INR](#), venous [ammonia](#), IL-6 and TNF-alpha at baseline, 30 days and at 60 days. All patients will also undergo psychometric testing with number connection test A, digit symbol test, block design and inhibitory control test at baseline and 60 days. Regular questioning about adherence to yogurt. Collection of yogurt tops as proof of yogurt consumption and review of intake diary will be done at 30 and 60 days from patients randomized to yogurt supplementation.

Interventions:

- Dietary Supplement: Yogurt Supplementation

Importance: There has been only one human study on the modification of gut flora as a [therapeutic](#) tool for improvement of MHE in cirrhosis, however that study included alcoholic [liver disease](#) and comprised of Chinese patients, therefore etiologies of liver diseases studied were different from those predominant in the United States. Since MHE can adversely affect quality of life and overall prognosis, simple, targeted therapies are needed to treat it. We believe that our pilot study will help delineate human gut flora as a definite target for therapy of cirrhosis and MHE and pave the way for future large-scale studies on this subject.

Eligibility

Gender

Inclusion Criteria:

Both

- [Cirrhosis](#) diagnosed on clinical grounds (within 3 months of enrollment)
- MHE diagnosed by abnormalities in a psychometric battery (NCT-A,BDT,DST and ICT)

Minimum Age

24 Years

Maximum Age

65 Years

Healthy Volunteers

No

Exclusion criteria:

- Current or recent (< 6 month) use of alcohol
- Co-existing cause of liver dysfunction
- Use of [antibiotics](#) within last 6 weeks
- Infection or [gastrointestinal](#) hemorrhage within the last 6 weeks
- Hepatocellular carcinoma
- Psychoactive drug use, including interferon concurrently

Resources

Source: Medical College of Wisconsin

Authority: United States: Institutional Review Board

Locations**GCRC Medical College of Wisconsin**

Milwaukee
Wisconsin
53226
United States

Officials

- Jasmohan S Bajaj, MD (Principal Investigator, Medical College of Wisconsin)

Sponsors

- Medical College of Wisconsin (Lead Sponsor)
- National Center for Research Resources (NCRR) (Collaborator)

References

None.

Links

None.

Date Verified

October 1st, 2007

First Received

October 31st, 2007

Last Changed

October 31st, 2007

Information obtained from ClinicalTrials.gov on July 15, 2008. [Link to the current ClinicalTrials.gov record.](#)

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