Healia Clinical Trials Information Database

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.

Description

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.

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.

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.

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.

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

Enrollment: 30 subjects

Study Type: Interventional

Study Design:

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

Conditions:

- Cirrhosis
- Minimal Hepatic Encephalopathy

Interventions:

- Dietary Supplement: Yogurt Supplementation

Eligibility

Inclusion Criteria:

Gender
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)

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

Mininum Age
24 Years

Maximum Age
65 Years

Healthy Volunteers
No

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.

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