Protocol Registration Receipt
09/02/2011

Fructose Malabsorption in Northern Norway (FINN)

This study is ongoing, but not recruiting participants.

Sponsor:	University Hospital of North Norway
Collaborators:	University Hospital of North Norway Nordlandssykehuset HF
Information provided by (Responsible Party):	University Hospital of North Norway
ClinicalTrials.gov Identifier:	NCT00555191

Purpose

Different published studies has shown a possible co-variation between leakage og fructose to the great bowel and exacerbation of irritable bowel syndrome (IBS) symptoms.

The aim of the FINN trial is to study the role of fructose malabsorption in patients with IBS in order to evaluate different diagnostic criteria for fructose malabsorption and at the same time study the effect of diet treatment in this cohort of patients and estimate the prevalence of fructose malabsorption.

Condition	Intervention	Phase
Irritable Bowel Syndrome Fructose Malabsorption	Behavioral: diet restriction	Phase 2/Phase 3

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Efficacy Study
Official Title: Fructose Malabsorption in Northern Norway. Fructose Malabsorption and Irritable Bowel Syndrome.

Further study details as provided by University Hospital of North Norway:

Primary Outcome Measure:

- VAS score og specific abdominal complaints.SGA score of relief related to abdominal complaints. [Time Frame: 12 weeks] [Designated as safety issue: No]

Secondary Outcome Measures:

- Estimate sensitivity,specificity,negative and positive predictive value using 50 gm fructose in breath test.Validate questionary for intolerance.Validate VAS in judging changes in abdominal complaint.Examine polymorphism i Glut5 transporter gene. [Time Frame: 12 weeks] [Designated as safety issue: No]

Estimated Enrollment: 400
Study Start Date: September 2007
Estimated Study Completion Date: March 2013
Estimated Primary Completion Date: October 2011

Arms	Assigned Interventions
Active Comparator: 1 PATIENTS IN THIS ARM IS INSTRUCTED IN FRUCTOSEREDUCED DIET	Behavioral: diet restriction each meal should contain less than 2 gm fructose
No Intervention: 2 these patients use their usual diet	

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- IBS patients satisfying ROME 2 diagnostic criteria

Exclusion Criteria:

- Seriously ill
- Organic abdominal disease
- Other functional bowel disease

Contacts and Locations

Locations

Norway

Hospital of Rana Medical Dep. Helgelandsykehuset HF
Mo i Rana, Nordland, Norway, 8607

Investigators

Principal Investigator:	Jon Florholmen, MD PhD	University Hospital of North Norway, Department of Gastroenterology

More Information

Responsible Party:	University Hospital of North Norway
Study ID Numbers:	N-136/2006(REK) 136/2006/REK-N 15567/NSD Ref 1204 Biobankregisteret
Health Authority:	Norway: The National Committees for Research Ethics in Norway; Norway: Norwegian Social Science Data Services; Norway: Directorate for Health and Social Affairs