Protocol Registration Receipt
07/07/2012

The Effects of Lactose Intolerance on Gastrointestinal Function and Symptoms in a Chinese Population

This study is currently recruiting participants.
Verified by DAI Ning, Sir Run Run Shaw Hospital, July 2012

Sponsor:	Sir Run Run Shaw Hospital
Collaborators:	University Hospital, Zürich
Information provided by (Responsible Party):	DAI Ning, Sir Run Run Shaw Hospital
ClinicalTrials.gov Identifier:	NCT01286597

Purpose

Lactose is a carbohydrate found in milk,and Lactase Deficiency (LD) is a condition in which the small intestine cannot digest this carbohydrate due to absent or insufficient amounts of lactase.Individuals with LD may be intolerant of lactose in the diet and experience abdominal cramps, bloating and diarrhea; however the response is variable.Some tolerate moderate amounts of lactose without adverse effect,whereas others experience severe symptoms in response to even small doses. These problems may be representative of wider issues regarding individual tolerance to diet containing ubiquitous poorly absorbed, fermentable carbohydrates (such as: fructose, fructans)and be relevant to symptom generated in patients with diarrhea predominant irritable bowel syndrome (D-IBS).

This project will investigate the effects of diet,lifestyle stress and psychiatric dietary on the development of functional gastrointestinal symptoms. Lactose will be used to assess tolerance to dietary challenge, a test that is particularly relevant in a Chinese population with a high prevalence of lactase deficiency.

Condition	Intervention	Phase
Lactose Intolerance	Dietary Supplement: dietary restriction	N/A

Condition	Intervention	Phase
Irritable Bowel Syndrome		

Study Type: Interventional
Study Design: Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Efficacy Study
Official Title: The Effects of Lactose Intolerance on Gastrointestinal Function and Symptoms in a Chinese Population

Further study details as provided by DAI Ning, Sir Run Run Shaw Hospital:

Primary Outcome Measure:

- To assess the effects of lactose intolerance on gastrointestinal function and symptoms [Time Frame: Three years] [Designated as safety issue: No]

Secondary Outcome Measures:

- To measure the intake of dietary lactose in the adult general population and in patients with IBS [Time Frame: three years] [Designated as safety issue: No]
- To assess genetic factors, tolerance to lactose challenge and visceral sensitivity. [Time Frame: three years] [Designated as safety issue: No]
- To assess appropriate dosage of lactose hydrogen breath test [Time Frame: two years] [Designated as safety issue: No]
- To determine the impact of a determined dietary intervention on abdominal symptoms compatible with D-IBS. [Time Frame: three years] [Designated as safety issue: No]
- To explore the association of visceral sensitivity induced by LI with mucosal immune activation and psychological factors in D-IBS patients [Time Frame: two years] [Designated as safety issue: No]

Estimated Enrollment: 3000
Study Start Date: January 2011
Estimated Study Completion Date: December 2012
Estimated Primary Completion Date: December 2012

Arms	Assigned Interventions
Experimental: dietary	Dietary Supplement: dietary restriction restrict intake of lactose Other Names: exclusion diet；food restriction；dietary treatment

Study #1: Questionnaire study in general Chinese population (n=2000).

Study #2: Physiologic study in patients attending gastroenterology clinic (n=600) including in subgroups assessment of genetic factors,tolerance to lactose challenge and assessment of visceral sensitivity.

Study #3: Assessment of appropriate dosage of lactose hydrogen breath test in a population with high-prevalence of lactase deficiency.

Study #4: Impact of a determined dietary intervention on abdominal symptoms compatible with D-IBS.

study #5: The association of visceral sensitivity induced by LI with mucosal immune activation and psychological factors in D-IBS patients

Eligibility

Ages Eligible for Study: 16 Years to 75 Years
Genders Eligible for Study: Both
Accepts healthy volunteers.

Inclusion Criteria:

1. Aged at least 16 years old and not more than 75 years old.
2. Ability to communicate with the investigator, complete study questionnaires (with help of investigator) and provide informed consent.

Exclusion Criteria:

1. Progressive, severe disease requiring active medical management (e.g. advanced cardiac, liver, renal or neurological disease, advanced cancer)
2. History of significant gastrointestinal pathology (other than gastro-oesophageal reflux disease and functional bowel diseases)
3. History of gastro-intestinal surgery (except appendicectomy, cholecystectomy, hernia repair).
4. Evidence of active drug or alcohol abuse

Contacts and Locations

Contacts

Ning DAI, MD 0086-13867457664 dainingcn@gmail.com

Locations

China, Zhejiang

Sir Run Run Shaw Hospital , College of Medicine, Zhejiang University, China Recruiting
Hangzhou, Zhejiang, China, 310016
Contact: Ning Dai, MD 0086-13867457664 dainingcn@gmail.com

Investigators

Study Chair: Ning DAI, MD — Sir Run Run Shaw Hospital, College of Medicine, Zhejiang University, China

More Information

Responsible Party: DAI Ning, Director of Gastroenterology department, Sir Run Run Shaw Hospital
Study ID Numbers: 120100047

Health Authority: China: State Food and Drug Administration