

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of exogenous lactase on reduction of lactose intolerance gastrointestinal symptoms in lactose intolerant patients compared with placebo

Protocol summary

Summary

It is a double blind, placebo controlled trial to assess the effect of exogenous lactase enzyme on reduction of lactose intolerance gastrointestinal symptoms in lactose intolerant patients. We studied 50 healthy symptomatic adults previously identified as being lactose intolerant by impaired h2 breath test. Each of subjects received lactase enzyme treatment for one week and placebo for equal time. The effectiveness of treatments was gathered by symptom evaluation questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902113740N1**
Registration date: **2010-05-21, 1389/02/31**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-21, 1389/02/31

Registrant information

Name

Behzad Asanjarani

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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asanjarani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2009-02-03, 1387/11/15

Expected recruitment end date

2009-09-06, 1388/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of exogenous lactase on reduction of lactose intolerance gastrointestinal symptoms in lactose intolerant patients compared with placebo

Public title

Assessment of exogenous lactase enzyme

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Positive lactose hydrogen breath test.

Exclusion criteria: Incorrect use of lactase enzyme

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Allamolhoda St., Shahid Shiroodi Avenue

City

Arak

Postal code

3819693345

Approval date

2009-01-19, 1387/10/30

Ethics committee reference number

87-46-4

Health conditions studied

1

Description of health condition studied

Lactose intolerance

ICD-10 code

E73

ICD-10 code description

Lactose intolerance

Primary outcomes

1

Description

Treatment of lactose intolerance

Timepoint

One week after intervention

Method of measurement

Symptom evaluation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

two oral capsules each contained starch before milk and dairy for one week

Category

Placebo

2

Description

two oral capsules each contained 3000 u lactase enzyme before milk and dairy for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroentorology Clinic, Valiasr Hospital

Full name of responsible person

Dr Behzad Asanjarani

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Ramin Ghahramani

Street address

Amiralmomenin Hospital

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Behzad Asanjarani

Position

Internal Medicine Resident

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Person responsible for updating data

Contact

Name of organization / entity**Full name of responsible person**

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Position**Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email****Web page address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Ramin Ghahremani

Position

Gastroenterologist

Other areas of specialty/work**Street address**

Amiralmomenin Hospital

City

Arak

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty