

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Study of lactulose effects in the treatment of non alcoholic fatty liver disease in comparison with vitamin E: A randomized, clinical trial

Protocol summary

Summary

The aim of this study is to investigate the effects of lactulose to decrease liver size in non-alcoholic fatty liver disease. Forty patients will be randomly assigned into intervention and control groups, each containing 20 subjects. Before and after end of the study will be measured liver size, liver enzymes levels and probiotic bacteria colony count of 2 grams of stool. Inclusion criteria: non-alcoholic fatty liver disease; age between 30 and 70 years. Exclusion criteria: antibiotic usage; presence of acute and chronic gastrointestinal diseases leading to intestinal dysfunction; use of medications affecting bowel function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010715879N3**

Registration date: **2015-02-08, 1393/11/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-08, 1393/11/19

Registrant information

Name

Reza Ghotaslou

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4661

Email address

gottasloreza@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-02-18, 1393/11/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of lactulose effects in the treatment of non alcoholic fatty liver disease in comparison with vitamin E:
A randomized, clinical trial

Public title

Lactulose effect in non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Non alcoholic fatty liver disease, age between 30 and 70 years. Exclusion criteria: Diabetic mellitus, viral hepatitis, congenital hepatitis, drug hepatitis, autoimmune hepatitis, alcohol use, blood triglyceride more than 500mg, inflammatory bowel diseases (Ulcerative colitis or Crohn's disease), chronic diarrhea, antibiotic use, contraindication of lactolus use, use of medications affecting bowel function, and consent to participate in the study.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will be randomly divided into two groups using the software Randlist 1.2.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Central building II ,Third floor, Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2014-07-20, 1393/04/29

Ethics committee reference number

9361

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Non alcoholic fatty liver disease

Primary outcomes

1

Description

Liver size

Timepoint

Baseline and one month after starting the study.

Method of measurement

Ultrasound sonography

Secondary outcomes

1

Description

Intestinal probiotic count

Timepoint

Baseline and one month after starting the study.

Method of measurement

Pour plate technique

2

Description

Drug complications

Timepoint

One month after starting the study.

Method of measurement

Ask the patient

Intervention groups

1

Description

Patients in the intervention group receive 20- 30cc lactulose daily for one month. Lactulose syrup (or Laxilose®, 10 g lactulose/15 mL, Alborzdaru) is a synthetic sugar used to treat constipation. In the colon, lactulose is metabolized primarily to lactic acid by bacteria that pull water out from the body and into the colon. Lactulose is also used to reduce the amount of ammonia in the blood of patients with liver disease. Lactulose poorly absorbed from the GI tract when given oral. Side effects of drug are diarrhea, gas, nausea, stomach pain or cramps and vomiting.

Category

Treatment - Drugs

2

Description

The intervention 2: Patients in control group receive vitamin E.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Seyed Yagoub Moaddab

Street address

Seyed Yagoub Moaddab, GI ward, Emam Reza Hospital, Daneshgah Street, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz university of medical sciences

Full name of responsible person

Mehdi Farhoudi

Street address

Central building II, Third floor, Golgasht Street, Tabriz University of Medical Sciences

City

Tabriz

Grant name

طرح تحقیقاتی

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tabriz 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**

Tabriz university of medical sciences

Full name of responsible person

Reza Ghotaslou

Position

Associated professor of clinical microbiology

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

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Reza Ghotaslou

Position

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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