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 تحقیقاتي
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
Department of microbiology, School of medicine, Tabriz, Iran
City
Tabriz
Postal code
Phone
+98 41 3336 4661
Fax
Email
rzgottaslo@yahoo.com
Web page address

Person responsible for scientific 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
Department of microbiology, School of medicine, Daneshgah street, Tabriz, East Azerbaijan, Iran
City
Tabriz
Postal code
Phone
+98 41 3336 4661
Fax
Email
rzgottaslo@yahoo.com
Web page address

Person responsible for updating data

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
Department of microbiology, School of medicine, Daneshgah street, Tabriz, East Azerbaijan, Iran
City
Tabriz
Postal code
Phone
+98 41 3336 4661
Fax
+98 41 3336 4661
Email
rzgottaslo@yahoo.com
Web page address

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