Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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
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Position
Associated professor of clinical microbiology
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Person responsible for updating data

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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