Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the role of Helicobacter pylori eradication in patients with non-alcoholic fatty liver disease on non-invasive criteria for liver fibrosis including FIB_4, NFS, BARD score

Protocol summary

Study aim

Determining the relationship between Helicobacter pylori eradication in patients with non-alcoholic fatty liver disease and FIB_4 NFS, BARD score

Design

Clinical trial without control group, without blinding, without randomization, phase 2 on 150 patients.

Settings and conduct

Patients with non-alcoholic fatty liver disease who referred to Tabriz Imam Reza Hospital clinic were selected based on the inclusion/exclusion criteria mentioned in other parts and with informed consent, Helicobacter pylori fecal antigen will be requested and if the antigen was positive We enter to the study and after obtaining sufficient information and relevant tests, the exact score of liver fibrosis is calculated based on the non-invasive criteria of liver fibrosis, and then Helicobacter pylori is eradicated with a 4-drug regimen, and again 6 months after the treatment, the exact score We calculate the non-invasive parameters of the liver and compare and check with the previous state.

Participants/Inclusion and exclusion criteria

1.Inclusion criteria: Patients with non-alcoholic fatty liver disease who are more than 18 years old and less than 65 years old 2. Exclusion criteria: alcoholics, under 18 years old, over 65 years old, people who have recently taken antibiotics or proton pump inhibitors, are excluded from the study.

Intervention groups

The intervention group includes patients with non-alcoholic fatty liver disease who receive Helicobacter pylori treatment intervention.

Main outcome variables

The NFS criterion ; The BARD score ; FIB-4 criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230221057484N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Mohammad Amin Gorbani Zirian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 2032

Email address

amin.gorbani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-21, 1402/06/30

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the role of Helicobacter pylori eradication in patients with non-alcoholic fatty liver disease on non-invasive criteria for liver fibrosis including FIB_4, NFS, BARD score

Public title
Evaluation of the role of Helicobacter pylori eradication in patients with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-alcoholic fatty liver disease who are more than 18 years old and less than 65 years old Patients whom despite full adherence to diet and lifestyle modification and appropriate physical activity for 6 months,There were no changes in the degree of fatty liver and liver enzymes and non-invasive measures of liver fibrosis
Exclusion criteria:
People who have a history of alcohol consumption People who have recently taken antibiotics People who have recently taken proton pump inhibitors
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz University of Medical Sciences
Street address
Faculty of Medicine, next to imam reza hospital . golgasht street
City
tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-06-28, 1400/04/07
Ethics committee reference number
IR.TBZMED.REC.1401.291

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
K75.8
ICD-10 code description
Other specified inflammatory liver diseases

Primary outcomes

1

Description
BARD score as a non-invasive criteria of liver fibrosis
Timepoint
The exact calculation of BARD score will be done two times (one time at the beginning, before the start of the intervention and the other 6 months after the eradication of Helicobacter pylori).
Method of measurement
calculation of score of non-invasive liver fibrosis criteria BARD score

2

Description
NFS score as a non-invasive criteria of liver fibrosis
Timepoint
The exact calculation of NFS will be done two times (one time at the beginning, before the start of the intervention and the other 6 months after the eradication of Helicobacter pylori).
Method of measurement
calculation of score of non-invasive liver fibrosis criteria NFS

3

Description
FIB_4 score as a non-invasive criteria of liver fibrosis
Timepoint
The exact calculation of FIB_4 will be done two times (one time at the beginning, before the start of the intervention and the other 6 months after the eradication of Helicobacter pylori).
Method of measurement
calculation of score of non-invasive liver fibrosis criteria FIB_4

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The People entered according to the entry and exit criteria, the level of body enzymes, the number of platelet, blood sugar were tested and with the help of age, height and weight, liver fibrosis scores (BARD score, NFS score, FIB-4) were determined and then will be treated with a four-drug regimen of Helicobacter pylori with metronidazole(Flagyl®) 400mg three times a day, bismuth(Bismuthan®) 220mg twice a day, amoxicillin(Amorax®) 1g three times a day and pentaprazole(Panzol®) 40mg once a day for 2 weeks and then 6 months After liver fibrosis scores (BARD score, NFS score, FIB-4) using body enzyme level tests, blood platelet count, blood sugar, age, height and weight will be calculated and compared with the previous score.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam reza hospital

Full name of responsible person
mohammad amin gorbani zirian

Street address
Tabriz .Golgasht St. facing the central organization of Imam Reza Educational and Medical Center University

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imamreza@tbzmed.ac.ir

Web page address
http://imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Daroush Savadi oskouei

Street address
Next to imam reza hospital,Golgasht sreet

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Email
info.medfac@tbzmed.ac.ir

Web page address
http://medfac.tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Amin Gorbani Zirian

Position
Medical student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

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Position
Medical student

Latest degree
A Level or less

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

What processes are involved for a request to access data/document

Comments