

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The study of treatment of Helicobacter Pylori in improvement of non-alcoholic fatty liver disease

Protocol summary

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Summary

Aim: assessment of any relationship between treatment of Helicobacter Pylori infection and improvement of fatty liver disease. inclusion criteria: patients with non-alcoholic fatty liver disease and Helicobacter Pylori infection. exclusion criteria: hypersensitivity to the prescribed drugs; non-consent to the participation to the study; study population: OPD patients attending in gastroenterology clinic, Velayat hospital; the sample size: 30; intervention: treatment of helicobacter pylori infection and assessment of its effect on improvement of fatty liver disease; duration of the study: 6 months; outcome measures: liver function test, liver sonography.

Recruitment status

Recruitment complete

Funding source

Research department of school of medicine; Qazvin university of medical sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-07-21, 1394/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

role of treatment of HP in improvement of NAFLD

IRCT registration information

IRCT registration number: **IRCT2015042020951N2**

Registration date: **2015-05-12, 1394/02/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-12, 1394/02/22

Registrant information

Name

Amir Mohammad Kazemifar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3335 6696

Email address

Scientific title

The study of treatment of Helicobacter Pylori in improvement of non-alcoholic fatty liver disease

Public title

Role of Helicobacter Pylori in treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Helicobacter Pylori Infection according to serologic test; Non-alcoholic fatty liver disease according to liver function tests and sonography; consent to participation in the study. Exclusion criteria: presence of any other medical disease; history of hypersensitivity to the prescribed drugs; non-consent to the participation to the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of research department of Qazvin university of medical sciences

Street address

Bahonar Blvd, the University paradise

City

Qazvin

Postal code

Approval date

2015-01-07, 1393/10/17

Ethics committee reference number

28/20/9669

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

2

Description of health condition studied

Helicobacter pylori infection

ICD-10 code

B98.0

ICD-10 code description

Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description

aspartate aminotransferase

Timepoint

at the start and end of the study

Method of measurement

by clinical laboratory

2

Description

alanine aminotransferase

Timepoint

at the start and end of the study

Method of measurement

by clinical laboratory

3

Description

sonographic indices of fatty liver disease

Timepoint

at the start and end of the study

Method of measurement

by a trained sonologist

Secondary outcomes

empty

Intervention groups

1

Description

Case group: treatment of Helicobacter Pylori with omeprazole (20 mg bid), amoxicillin (1gr bid), and clarithromycin (500 mg bid) orally for 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: will receive only symptomatic therapy, if indicated; for example digestive tablet if complained from indigestion. Treatment of helicobacter pylori will be postponed until the end of the study (if the patients provide informed consent).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic, Velayat hospital

Full name of responsible person

Elahe Hajinourmohammadi

Street address

Minoodar district

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

research department of medical college of QUMS

Full name of responsible person

Mahnaz Abbasi

Street address

Bahonar Blvd, the university paradise

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

research department of medical college of QUMS

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

Qazvin University of Medical Sciences

Full name of responsible person

Elahe Hajjournmohammadi

Position

resident of internal medicine

Other areas of specialty/work

Street address

Buali hospital, Buali St.

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elahemehr@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Aliakbar Hajaghamohammadi

Position

Gastroenterologist

Other areas of specialty/work

Street address

Velayat hospital, Minoodar District

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ahmohammadi@qums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Mohammad Kazemifar

Position

toxicologist

Other areas of specialty/work

Street address

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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