Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

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

Protocol summary

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 of fatty liver disease; duration of the study: 6 months; outcome measures: liver function test, liver sonography.

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
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Iran (Islamic Republic of)
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amkazemifar@qums.ac.ir

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

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 labratory

2

Description
alanine aminotransferase
Timepoint
at the start and end of the study
Method of measurement
by clinical labratory

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), amoxicilin (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 Medica Sciences

Full name of responsible person

Elahe Hajinourmohammadi

Position

resident of internal medicine

Other areas of specialty/work

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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 Siences

Full name of responsible person

Aliakbar Hajaghamohammadi

Position

Gastroenterologist

Other areas of specialty/work

Street address

Velayat hospital, Minoodar District

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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

Buali hospital, Buali St.

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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