Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

study of effects of helicobacter pylori infection on improvement of metabolic syndrome

Protocol summary

Summary

Aim: assessment of any relationship between helicobacter pylori infection and metabolic syndrome. Inclusion criteria: patients with metabolic syndrome and infection with helicobacter pylori. Exclusion criteria: non-consent to participation in the study; any other internal or cardiac disease; intolerance to the prescribed drugs Study population: outpatient persons attending in internal medicine clinic with diagnosis of metabolic syndrome and infection with helicobacter pylori. the sample size: 80 Intervention: treatment of helicobacter pylori infection and its impact on improvement of metabolic syndrome. duration of the study: 6 months primary outcome measures: indices of metabolic syndrome including body mass index, serum triglyceride concentration, waist circumference, blodd pressure.

General information

Acronym

helicobacter pylori and metabolic syndrome

IRCT registration information

IRCT registration number: **IRCT2015020420951N1**
Registration date: **2015-03-09, 1393/12/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-09, 1393/12/18

Registrant information

Name

Amir Mohammad Kazemifar

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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amkazemifar@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research department of medicine college of Qazvin University of Medical Silences; Taghi Naserpour Farivar

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study of effects of helicobacter pylori infection on improvement of metabolic syndrome

Public title

the effect of treatment of helicobacter pylori (HP) infection on improvement of metabolic syndrome (MS)

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: concomitant metabolic syndrome and helicobacter pylori exclusion: no consent; any other internal or cardiac disease; intolerance to the prescribed drugs

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

28/20/9672

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

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

waist circimference

Timepoint

at the start and end of the study

Method of measurement

cm

2

Description

fasting blood sugar

Timepoint

at the start and end of the study

Method of measurement

mg/dl

3

Description

serum triglyceride

Timepoint

at the start and end of the study

Method of measurement

mg/dl

4

Description

blood pressure

Timepoint

at the start and end of the study

Method of measurement

milimeter of mercury

5

Description

body mass index

Timepoint

at the start and end of the study

Method of measurement

kg/m2

Secondary outcomes

empty

Intervention groups

1

Description

case group: treatment of HP infection woth opemrazole (20 mg bid), amoxicilin (1gr bid), and clarythromycin (500 mg bid)

Category

Treatment - Drugs

2

Description

the control group will receive only symptomatic therapy.

the HP treatment postponed until the end of the study (if they provide informed consent)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

outpatient treatment center of QUMS

Full name of responsible person

Zahra Azariun

Street address

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

Zahra Azariun

Position

resident of internal medicine

Other areas of specialty/work

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Buali hospital, Buali St.

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Person responsible for scientific inquiries

Contact

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Bahram Mehrtash

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Internist

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Name of organization / entity

Qazvin University of Medical Sciences

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Position

toxicologist

Other areas of specialty/work

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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