

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Determining the relationship between Helicobacter pylori eradication treatment and blood sugar control in type 2 diabetic patients

Protocol summary

Study aim

Determining the relationship between eradication of h.pylori infection and blood sugar control in type 2 diabetic patients

Design

The clinical trial has a control group, three-blind, randomized, on 108 patients, sampling is done by the available method. Then they are divided into two groups by Balanced Block Randomization method.

Settings and conduct

Diabetic patients referred to Velayat Hospital with positive H.pylori test are divided into intervention and control groups by Balanced Block Randomization. The blocks are randomly arranged as AABB, BBAA, ABBA, BAAB, ABAB, BABA in the number of 54 blocks. Group A will be treated and group B will be the control. The level of HbA1c and FBS before starting the treatment of H.pylori infection and after proving its eradication by determining the antigen of H.pylori in feces by PCR method, measuring HbA1c again 3 months after the start of treatment. and the difference between HbA1c and FBS before and after treatment is compared. In the control group, the levels of HbA1c and FBS are measured in stages 1 and 2. During this period, they do not receive Helicobacter eradication therapy. the patients, the attending physician and the analyst do not know how to choose the patients, the study is triple blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: All asymptomatic diabetic patients with a positive Helicobacter pylori test
Exit criteria: People with kidney failure, anemia and hemoglobinopathy
History of antibiotic use in the past one month and proton pump inhibition in the past two weeks
Helicobacter infection treatment history
HbA1C greater than 10
Diabetic patients needing insulin treatment

Intervention groups

Intervention group: patients treated with a four-drug anti-H.pylori regimen of bismuth+metronidazole+amoxicillin+omeprazole for 2

weeks. Control group: patients receiving placebo

Main outcome variables

Determination of blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220920056004N1**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Taha Rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3323 3285

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining the relationship between Helicobacter pylori eradication treatment and blood sugar control in type 2 diabetic patients

Public title
Determining the relationship between Helicobacter pylori eradication treatment and blood sugar control in type 2 diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All asymptomatic diabetic patients whose Helicobacter pylori test is positive Informed consent of the patient regarding participation in the study
Exclusion criteria:
People with kidney failure, anemia and hemoglobinopathy History of antibiotic use in the last one month and proton pump inhibitor in the last two weeks Patients who had a history of treatment for Helicobacter infection in the past Patients who have hb a1c more than 10 Diabetic patients needing insulin treatment

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is conducted as a Randomized Clinical Trial on all diabetic patients who visited Qazvin Provincial Hospital during the years 1402-1401. Diabetic patients in whom Helicobacter pylori infection was proven were divided into two groups by the Balanced Block Randomization method. Intervention and control will be divided. The blocks will be randomly arranged in the form of AABB, BBAA, ABBA, BAAB, ABAB, BABA in the number of 54 blocks. Group A will be treated and group B will be the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
Considering that the patients do not know in which group they will be placed and that the attending physician will select the control and intervention groups based on random allocation and the person who performs the statistical analysis does not know how to select the patients, the study is a blinded study.

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences
Street address
Research and technology deputy, Mavaddat Alley, Shahid Beheshti Blvd, Qazvin , Iran
City
Qazvin
Province
Qazvin
Postal code
3415613911

Approval date
2022-09-04, 1401/06/13

Ethics committee reference number
IR.QUMS.REC.1401.166

Health conditions studied

1

Description of health condition studied
Helicobacter pylori

ICD-10 code
B96.81

ICD-10 code description
Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

2

Description of health condition studied
Type 2 diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Determination of blood sugar

Timepoint
The level of HbA1c and FBS before starting the treatment of Helicobacter pylori infection and after proving its eradication with the determination of Helicobacter pylori

antigen in stool by PCR method, HbA1c is measured again three months after the start of treatment and the difference between HbA1c and FBS before and after treatment is compared

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group will be treated with a four-drug anti-Helicobacter pylori regimen of bismuth + metronidazole + amoxicillin + omeprazole for 2 weeks. Diagnosing diabetes is based on serum sugar equal to or above 126 (14) HbA1c is measured by ELISA method (Diaplus Company) and FBS by glucose oxidase method (Man Company).

Category

Treatment - Drugs

2**Description**

Control group: In the control group, HbA1c and fasting blood sugar (FBS) are measured in two stages 1 and 2. During this period, they do not receive the Helicobacter eradication regimen.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat hospital

Full name of responsible person

Taha Rezaiyan

Street address

Velayat hospital, 22 Bahman Blvd., Minoodar Town

City

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3471976161

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mehdi Mirhashemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Taha Rezaiyan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

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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

Undecided - It is not yet known if there will be 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