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
taharezaiyan@gmail.com

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
Qazvin

Province
Qazvin

Postal code
3471976161

Phone
+98 28 3379 0620

Email
m.nazarinia99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Mehdi Mirhashemi

Street address
Bahonar street

City
Qazvin

Province
Qazvin

Postal code
34197-59811

Phone
+98 28 3333 6001

Email
medicine@qums.ac.ir

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 Rezayian

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

Street address
Bahonar street

City
Qazvin

Province
Qazvin

Postal code
34197-58911

Phone
+98 28 3333 6001

Email
taharezaiyan@gmail.com

Person responsible for scientific 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

Street address
Bahonar street

City
Qazvin

Province
Qazvin

Postal code
34197-58911

Phone
+98 28 3333 6001

Email
taharezaiyan@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Taha rezaiyan

Position
Resident

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Internal Medicine

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Province
Qazvin

Postal code
34197-58911

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Email
taharezaiyan@gmail.com

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