

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Helico bacter pylori treatment on decrease the insulin resistance and dose of insulin in diabetic person in kerman

Protocol summary

Study aim

Determining the effect of H-pylori infection treatment on reducing insulin resistance and drug dosage in diabetic patients

Design

150 patients with diabetes and Helicobacter infection are first subjected to standard treatment, after the completion of the treatment with breath test/stool antigen, eradication is confirmed. Then patients are referred to an endocrinology specialist. 3 months after proving eradication of infection and without any change in the drug regime controlling diabetes and lifestyle changes, by FPS and hemoglobin A1C and BP and weight are evaluated. Then, effectiveness of infection treatment is evaluated and compared with the level of these parameters before the eradication of the infection.

Settings and conduct

A quasi-clinical trial study that will be conducted in the second half of 2023 on diabetic patients referred to Afzalipur Hospital, endocrinology clinic and endocrinology specialist office.

Participants/Inclusion and exclusion criteria

Entry: age over 18 and under 60 years; definitely suffering from diabetes based on reliable sources Failure to enter: unwillingness to participate in the study; suffering from hemoglobinopathies

Intervention groups

Patients with diabetes and Helicobacter infection who receive standard treatment, after treatment with breath test/stool antigen, eradication is confirmed. Then patients are referred to an endocrinologist. 3 months after proving the eradication of the infection and without changing the drug regimen controlling diabetes and changing the lifestyle, the patient was tested by FPS and hemoglobin A1C and BP and weight is assessed. Then, the effectiveness of infection treatment is evaluated and compared with the level of these parameters before the eradication of this infection.

Main outcome variables

The effect of H-pylori infection treatment on reducing insulin resistance and drug dosage in diabetic patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230624058567N1**

Registration date: **2023-06-26, 1402/04/05**

Registration timing: **prospective**

Last update: **2023-06-26, 1402/04/05**

Update count: **0**

Registration date

2023-06-26, 1402/04/05

Registrant information

Name

Omid Eslami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7470

Email address

o.eslami@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-15, 1402/04/24

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Helico bacter pylori treatment on decrease the insulin resistance and dose of insulin in diabetic person in kerman

Public title

The effect of Helico bacter pylori treatment on decrease the insulin resistance and dose of insulin in diabetic person in kerman

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years and under 60 years Definite diagnosis of diabetes based on reliable sources

Exclusion criteria:

Unwillingness to participate in the study
Hemoglobinopathy

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipur Medical Education Center, Clinical Research Development Unit

City

Kerman

Province

Kerman

Postal code

7616913911

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.KMU.AH.REC.1401.259

Health conditions studied**1****Description of health condition studied**

Helicobacter pylori infection, diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Reducing insulin resistance and drug dosage

Timepoint

Three months after proving the eradication of the infection and without changing the drug regimen controlling diabetes and changing the lifestyle, the patient was tested by fasting plasma sugar and hemoglobin A1C in the same primary laboratory before treatment and tests related to the development of metabolic syndrome, including blood pressure and The patient's weight is assessed. Then, the effectiveness of infection treatment is evaluated on these parameters and compared with the level of these parameters before the eradication of this infection.

Method of measurement

Three months after proving the eradication of the infection and without changing the drug regimen controlling diabetes and changing the lifestyle, the patient was tested by fasting plasma sugar and hemoglobin A1C in the same primary laboratory before treatment and tests related to the development of metabolic syndrome, including blood pressure and The patient's weight is assessed. Then, the effectiveness of infection treatment is evaluated on these parameters and compared with the level of these parameters before the eradication of this infection.

Secondary outcomes

empty

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

Intervention group: Patients whose diabetes has already been confirmed and the presence of Helicobacter infection in them has been confirmed by fecal antigen

tests are first treated with standard treatment, and after the treatment is completed with a breath test or fecal antigen, their eradication is confirmed. . Then the patients are referred to an endocrinology specialist to check their diabetes conditions, and then three months after proving that the infection has been eradicated and without any change in the diabetes control drug regimen and lifestyle changes, the patient is tested by fasting plasma sugar and hemoglobin. A1C is evaluated in the same primary laboratory before treatment and tests related to the development of metabolic syndrome, including blood pressure and patient weight, and then the effectiveness of infection treatment is evaluated on these parameters and compared with the level of these parameters before the eradication of this infection.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Amir Hossein Delkash

Street address

Imam Khomeini Highway, next to Shahid Bahonar University, Afzalipur Medical Education Center

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Email

amirdelkash1990@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpour

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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7616913555

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Amir Hossein Delkash

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total data

When the data will become available and for how long

Starting six months after the publication of the article

To whom data/document is available

Researchers, students and doctors

Under which criteria data/document could be used

To perform clinical examination

From where data/document is obtainable

General or scientific responsible person

What processes are involved for a request to access data/document

Submit the proposal to the responsible person

Comments