

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of celecoxib on alleviation of gastric intestinal metaplasia in patients with positive helicobacter pylori

Protocol summary

Study aim

Investigating the effect of celecoxib on the alleviation of gastric metaplasia

Design

Clinical trial with control group, with parallel groups, one-sided blind, phase, on 80 patients, block randomization

Settings and conduct

80 patients with gastric metaplasia according to OLGA (stages 1 to 4), referred to the gastroenterology clinic of Taleghani Hospital, will enter the project. First, patients undergo endoscopy and biopsy, and the patients' creatinine level is measured. Patients will be randomly divided into control and case groups. In the control group, four drugs of Helicobacter pylori are prescribed for 40 patients. In the case group, 40 patients will simultaneously receive a four-drug regimen of Helicobacter pylori along with celecoxib 100 mg. Helicobacter diet for two weeks and celecoxib drug for three months are prescribed for patients. After three months, the patients again undergo endoscopy and biopsy and are examined both in terms of eradication of Helicobacter and in terms of metaplasia according to OLGA. This study is one-sided blind, so that the person analyzing does not know about which patient the information is related to.

Participants/Inclusion and exclusion criteria

inclusion criteria: Helicobacter pylori positive, confirming the diagnosis of grade 1 to 4 gastric metaplasia

Exclusion criteria: allergy to celecoxib or esomeprazole

Intervention groups

In the case group, patients will receive a four-drug regimen of Helicobacter pylori plus celecoxib 100 mg. In the control group, a regimen of four Helicobacter pylori drugs (omeprazole, amoxicillin, clarithromycin and metronidazole) is prescribed.

Main outcome variables

Helicobacter pylori eradication, improving the grade of gastric metaplasia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057842N1**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Pardis Ketabi Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2525

Email address

ketabimoghadam.p@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of celecoxib on alleviation of gastric intestinal metaplasia in patients with positive helicobacter pylori

Public title

The effect of celecoxib in the treatment of gastric metaplasia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 years old All patients were diagnosed with gastric metaplasia

Exclusion criteria:

Patients with malignancy Patients who had been treated with regular nonsteroidal anti-inflammatory drugs (NSAIDs), proton-pump inhibitors, bismuth salts, or antibiotics within two weeks before endoscopy heart failure renal dysfunction pregnancy liver cirrhosis

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to two arms, using block randomization method. The block size is four, involving patients would be based on order's coming) which would generated by online block randomization software "Sealed Envelope". The list of random blocks will be placed in envelopes, daily would be opened by the staffs.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this design, the data analyst is subject to blinding, so he/she does not know that each data is related to which patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Gastroenterology and Liver Research Institute of Shahid Beheshti University of M

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.SBMU.RIGLD.REC.1401.037

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

gastric intestinal metaplasia

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

gastric metaplasia alleviation

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

endoscopy and biopsy result

2**Description**

helicobacter pylori eradication

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

endoscopy and biopsy result

Secondary outcomes**1****Description**

Improvement of dyspepsia symptoms

Timepoint

Before the intervention and three months after the intervention

Method of measurement

Dyspepsia symptom assessment questionnaire

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

Intervention group: In this group, patients will simultaneously receive the four-drug regimen of Helicobacter pylori, including omeprazole 20 mg, amoxicillin 500 mg, metronidazole 500 mg, and clarithromycin 500 mg along with celecoxib 100 mg (Hakim Company).

Category

Treatment - Drugs

2

Description

Control group: In the control group, only the four-drug regimen of Helicobacter pylori including omeprazole 20 mg, amoxicillin 500 mg, metronidazole 500 mg, and clarithromycin 500 mg is prescribed for patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology and Liver Clinic of Taleghani Hospital

Full name of responsible person

Mohammad Javad Ehsani Ardakani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Fallahnia

Position

gastroenterologist specialist assistant

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only the information related to the study protocol, the statistical analysis plan and the clinical study report will be made available to the requestors (and not publicly) to other researchers for guidance for further studies.

When the data will become available and for how long

after publishing the article

To whom data/document is available

Researchers, students and professors in the field of gastroenterology

Under which criteria data/document could be used

In order to be used in future research and if reference is mentioned

From where data/document is obtainable

corresponding author Amir Fallahnia
drafallahnia@yahoo.com

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

Sending a request via email to the responsible author and stating the reason for the request and how to use the data

Comments