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)

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+98 21 2243 2525

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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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Arabi street, Velenjak

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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

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact
Name of organization / entity
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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