

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Investigating the effect of *Helicobacter pylori* treatment regimen on improving pain and arthritis symptoms in patients with osteoarthritis

Protocol summary

Study aim

Determining the effect of H.pylori treatment regimen on improving pain and arthritis symptoms in patients with osteoarthritis

Design

The clinical trial with a control group, with parallel groups, without blinding and randomization, phase 3 will be completed on 60 patients.

Settings and conduct

60 patients with osteoarthritis referred to Hajar-Kashani Hospital-Imam Ali Clinic in Shehirkord will be included in the study. In addition to the common treatment of osteoarthritis, the H pylori positive group (intervention) will be given a *Helicobacter pylori* treatment regimen for 5 days. After 4 weeks from the start of the treatment, the eradication of *Helicobacter* is checked in order to classify the intervention group into two sub-groups, eradicated and not eradicated. 8 weeks after the start of the treatment, the stability of the effect of *Helicobacter pylori* eradication on the improvement of arthritis symptoms and pain in patients with osteoarthritis will be investigated in the intervention group where *Helicobacter* eradication has been proven.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 50 years; diagnosis of osteoarthritis according to x-ray, examination and clinical diagnosis of a specialist; presence of positive *Helicobacter pylori* infection; patient's consent to enter the study. Exclusion criteria: presence of immunodeficiency disease, active cancer and other rheumatological diseases in the patient; recent use of antibiotics

Intervention groups

Intervention group: patients with osteoarthritis who are H pylori positive-Receive standard treatment of osteoarthritis and H pylori treatment regimen
Control group: patients with osteoarthritis who are H pylori negative-Receive standard treatment for osteoarthritis

Main outcome variables

Severity of Pain;disease activity;joint stiffness;quality of life;physical performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231216060428N1**

Registration date: **2024-01-24, 1402/11/04**

Registration timing: **prospective**

Last update: **2024-01-24, 1402/11/04**

Update count: **0**

Registration date

2024-01-24, 1402/11/04

Registrant information

Name

Ghazaleh Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

ghazaleh.heidari.1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-27, 1402/11/07

Expected recruitment end date

2024-04-18, 1403/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Helicobacter pylori treatment regimen on improving pain and arthritis symptoms in patients with osteoarthritis

Public title
Investigating the effect of Helicobacter pylori treatment regimen on osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 50 years Osteoarthritis diagnosis according to the findings of the graphy, examination and Clinical diagnosis of a specialist doctor Presence of positiveHelicobacter pylori infection based on endoscopy, fecal antigen test or serum antibody Patient consent to enter the study
Exclusion criteria:
The presence of immunodeficiency disease, active cancer and other rheumatological diseases in the patient lack of consent to participate and the patient's request to withdraw from the research plan recent use of antibiotics

Age
From 50 years old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Medicine,Shahrekord University of Medical Sciences
Street address
Headquarters of Shahrekord University of Medical

Science,Kashani street.Shahrekord,Charmahal va Bakhtiari ,Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2024-01-03, 1402/10/13
Ethics committee reference number
IR.SKUMS.MED.REC.1402.076

Health conditions studied

1

Description of health condition studied
Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Severity of Pain
Timepoint
Measurement of pain severity before the intervention and 4 and 8 weeks after the intervention
Method of measurement
WOMAC questionnaire, ten-point visual assessment of pain intensity (VAS), 5-question European quality of life (EQ-5D-3L)

2

Description
Joint stiffness
Timepoint
before the intervention and four and eight weeks after starting Helicobacter pylori treatment regimen
Method of measurement
WOMAC questionnaire

3

Description
Disease activity
Timepoint
before the intervention and four and eight weeks after starting Helicobacter pylori treatment regimen
Method of measurement
WOMAC questionnaire

4

Description
Quality of Life

Timepoint

before the intervention and Four and eight weeks after starting Helicobacter pylori treatment regimen

Method of measurement

Ten-point visual assessment of pain intensity (VAS), 5-question European quality of life (EQ-5D-3L)

5**Description**

Physical performance

Timepoint

Measurement of Physical performance before the intervention and 4 and 8 weeks after the intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

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

Intervention group: people suffering from osteoarthritis, whose presence of positive Helicobacter pylori has been proven by endoscopy, fecal test or serology test. For this group, in addition to the common treatment of osteoarthritis, Helicobacter pylori treatment regimen includes: levofloxacin 500 mg per day from Abidi Pharmaceutical Company, amoxicillin 1 gram twice a day from Farabi Pharmaceutical Company and PPI (standard dose) twice a day from Abidi Pharmaceutical Company and tinidazole 500 mg twice a day Tehran Daru Pharmaceutical Company for 5 days is also give

Category

Treatment - Drugs

2**Description**

Control group: People with osteoarthritis in whom Helicobacter pylori has been proven negative by endoscopy, fecal test or serology test

Category

Treatment - Other

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

Hajar hospital/ Kashani hospital /Emam Ali clinic

Full name of responsible person

Ghazaleh Heidari Soodejani

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Parastar street

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Reisi

Street address

Kashani street

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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

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Ghazaleh Heidari Soodejani

Position

Resident of Internal Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Shahin Askari Savadjani

Position

Faculty of Assistant Professors

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

Our data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If there are conditions, all our data will be shared except personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address ghazaleh.heidari.1992@gmail.com or the contact number 00989131889039

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments