

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Therapeutic effect of the regiment of helicobacter pylori treatment on the improvement of pain and symptoms of arthritis in patients with rheumatoid arthritis

Protocol summary

Study aim

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

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

RA patients referred to Hajar Hospital, their severity of disease is mild to moderate, will be included in the study by the rheumatologist. The patients will be divided into intervention and control groups according to the presence of H. pylori infection. This study will be conducted without blinding. the H.pylori +group (intervention), receive common treatment of RA and H.pylori treatment (Levofloxacin 500 mg, amoxicillin 1 mg, tinidazole 500 mg and pantoprazole 40 mg every 12 hours for 5 days). After 4 weeks from the beginning of the treatment, the eradication of H.pylori is checked to classify into eradicated and not eradicated subgroups. finally, 8 weeks after the start of treatment, we check all of Main outcome variables In order to check the stability of the eradication effect of Helicobacter pylori.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People with mild to moderate rheumatoid arthritis according to the EULAR /criteria Presence of positive H pylori infection Exit criteria: Patient non-cooperation/Severe rheumatoid arthritis and the use of biological drugs in the treatment of RA/Suffering from other systemic diseases that are caused by surgery on the digestive system, synovectomy, and pregnancy

Intervention groups

Intervention group: Rheumatoid arthritis patients with H. pylori infection Control group: Rheumatoid arthritis patients that h.pylori negative

Main outcome variables

Patients' pain level, disease activity score, number of tender joints, morning stiffness, number of swollen joints, serum level of ESR, CRP, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060313N1**

Registration date: **2024-01-10, 1402/10/20**

Registration timing: **prospective**

Last update: **2024-01-10, 1402/10/20**

Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

Name

Ardalan Memar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3337 0157

Email address

ardalanmemar@yahoo.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
Therapeutic effect of the regiment of helicobacter pylori treatment on the improvement of pain and symptoms of arthritis in patients with rheumatoid arthritis

Public title
Therapeutic effect of the regiment of helicobacter pylori treatment on the improvement of pain and symptoms of arthritis in patients with rheumatoid arthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Patients with mild to moderate rheumatoid arthritis diagnosed by EULAR criteria (under traditional treatment with DMARD) Willingness to participate in the clinical trial Presence of positive H pylori infection based on endoscopy, fecal antigen or serum antibody test No recent use of antibiotics Absence of immunodeficiency diseases and active cancer Having an indication for the treatment of Helicobacter pylori infection
Exclusion criteria:
The patient's unwillingness to participate in the clinical trial death of the patient Severe rheumatoid arthritis and the use of biological drugs in the treatment of RA Patients with other systemic diseases, who have gastrointestinal surgery, have an active gastric ulcer, or synovectomy in any major joint. pregnancy

Age
From **18 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
Sciences,Kashani Street, Shahrekord, Chaharmahal
va Bakhtiary, 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.1402.077

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

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

Visual Analogue Scale (VAS) Questionnaire

2

Description

Disease activity

Timepoint

Measurement of Disease activity before the intervention
and 4 and 8 weeks after the intervention

Method of measurement

DAS-28 Questionnaire

3

Description

Tender joints

Timepoint

Measurement of Tender joints before the intervention

and 4 and 8 weeks after the intervention

Method of measurement

DAS-28 Questionnaire

4

Description

swollen joints

Timepoint

Measurement of swollen joints before the intervention and 4 and 8 weeks after the intervention

Method of measurement

DAS-28 Questionnaire

5

Description

Morning stiffness

Timepoint

Measurement of morning stiffness before the intervention and 4 and 8 weeks after the intervention

Method of measurement

DAS-28 Questionnaire

6

Description

Serum level of C-reactive protein

Timepoint

Measurement of Serum level of C-reactive protein before the intervention and 4 and 8 weeks after the intervention

Method of measurement

Measurement Serum level of C-reactive protein with a Flame Photometer

7

Description

Serum level of ESR

Timepoint

Measurement of Serum level of ESR before the intervention and 4 and 8 weeks after the intervention

Method of measurement

Measurement of serum ESR level with a Flame Photometer

8

Description

Quality of life

Timepoint

Measuring different aspects of quality of life before the intervention and 4 and 8 weeks after the intervention

Method of measurement

HAQ , EQ-5D Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with rheumatoid arthritis whose presence of Helicobacter pylori has been proven by endoscopy or stool test or positive Helicobacter pylori serology test.

Category

Treatment - Drugs

2

Description

Control group: patient with rheumatoid arthritis in whose Helicobacter pylori has been proven negative by endoscopy or fecal test or negative serology test.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hajar hospital

Full name of responsible person

Ardalan Memar

Street address

parastar street

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Phone

+98 913 929 1792

Email

ardalanmemar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Reisi

Street address

Parastar street

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8813833435

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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

Ardalan Memar

Position

Resident

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 Asgari

Position

Rheumatologist

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Email

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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 ardalanmemar@yahoo.com or the contact number 00989139291792

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