Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 /criteriaPresence 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 stifness 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

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Chahar-Mahal-va-Bakhtiari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

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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
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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
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