

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of topical ointment containing Berberis vulgaris' extract versus placebo on the severity of morning stiffness and range of motion in rheumatoid arthritis patients: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of a topical ointment containing Berberis vulgaris' extract versus placebo on the severity of morning stiffness and range of motion in rheumatoid arthritis patients

Design

This is a double-blind randomized clinical trial, phase II, in which 60 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible rheumatoid arthritis patients who will refer to Shahid Beheshti Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 60 years, Rheumatoid arthritis Exclusion criteria: Using narcotic substance or alcohol

Intervention groups

Intervention group: Routine treatment plus using Eucerin-based ointment containing hydroalcoholic Berberis vulgaris' extract at 10% concentration, manufactured by the laboratory of the School of Pharmacy, Hamadan University of Medical Sciences, twice daily for 15 days Control group: Routine treatment plus using Eucerin-based ointment without any additional medication, manufactured by the laboratory of the School of Pharmacy, Hamadan University of Medical Sciences, twice daily for 15 days

Main outcome variables

Primary outcome: The severity of morning stiffness of the joint, the range of motion of the joint

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N310**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **prospective**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical ointment containing Berberis vulgaris' extract versus placebo on the severity of morning stiffness and range of motion in rheumatoid arthritis patients: a double-blind randomized clinical trial

Public title

The effect of topical ointment containing Berberis vulgaris' extract versus placebo on the severity morning stiffness and range of motion in rheumatoid arthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 60 years, Rheumatoid arthritis

Exclusion criteria:

Using narcotic substance or alcohol

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.425

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

The severity of morning stiffness of the joint

Timepoint

Before the intervention and 15 days after that

Method of measurement

By Visual Analog Scale (VAS)

2

Description

The range of motion of the joint

Timepoint

Before the intervention and 15 days after that

Method of measurement

By physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment plus using Eucerin-based ointment containing hydroalcoholic Berberis vulgaris' extract at 10% concentration, manufactured by the laboratory of the School of Pharmacy, Hamadan University of Medical Sciences, twice daily for 15 days

Category

Treatment - Drugs

2

Description

Control group: Routine treatment plus using Eucerin-based ointment without any additional medication, manufactured by the laboratory of the School of Pharmacy, Hamadan University of Medical Sciences, twice daily for 15 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital in Hamadan City

Full name of responsible person

Fatemeh Soleimani

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Shahid Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Fatemeh Soleimani

Position

Student of Nursery

Latest degree

Master

Other areas of specialty/work

Nursery

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

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Full name of responsible person

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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