Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the pain-relief effect of herbal ointment versus piroxicam gel in patients with musculoskeletal pain: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To compare the pain-relief effect of herbal ointment versus piroxicam gel in patients with musculoskeletal pain. Design: A triple blind randomized clinical trial. Setting and conduct: The eligible patients with musculoskeletal pain who will refer to Shahid Mobasher Kashani Clinic during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 70 years; musculoskeletal pain. Exclusion criteria: Pregnancy and breastfeeding; cutaneous disease; sensitivity of herbal compound. Intervention group: Topical using herbal ointment twice a day for one week. Control group: Topical using piroxicam gel twice a day for one week. Primary outcome: Severity of the pain using visual analog scale (VAS) before intervention and one and three weeks after treatment. Secondary outcome: Morning stiffness through taking history before intervention and one and three weeks after treatment Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708029014N177**
Registration date: **2017-08-05, 1396/05/14**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-05, 1396/05/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the pain-relief effect of herbal ointment versus piroxicam gel in patients with musculoskeletal pain: a triple blind randomized clinical trial

Public title

Comparison of the pain-relief effect of herbal ointment versus piroxicam gel in patients with musculoskeletal

pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 70 years; musculoskeletal pain. Exclusion criteria: Pregnancy and breastfeeding; cutaneous disease; sensitivity of herbal compound.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

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 the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

Postal code

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.UMSHA.REC.1396.345

Health conditions studied

1

Description of health condition studied

Musculoskeletal pain

ICD-10 code

M95

ICD-10 code description

Other acquired deformities of musculoskeletal system and connective tissue

Primary outcomes

1

Description

Severity of the pain

Timepoint

before intervention and one and three weeks after treatment

Method of measurement

using visual analog scale (VAS)

Secondary outcomes

1

Description

Morning stiffness

Timepoint

before intervention and one and three weeks after treatment

Method of measurement

through taking history

Intervention groups

1

Description

Intervention group: Topical using herbal ointment twice a day for one week.

Category

Treatment - Drugs

2

Description

Control group: Topical using piroxicam gel twice a day for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mobasher Kashani Clinic

Full name of responsible person
Dr Bijan Heidari
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Shahid Mobasher Kashani Clinic, Mahdieh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research and Technology, Hamadan 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
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code

empty

Data Dictionary

empty