

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

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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

City

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

Street address

Shahid Mobasher Kashani Clinic, Mahdieh Ave.

City

Hamadan

d.dastan@umsha.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Mobasher Kashani Clinic

Full name of responsible person

Dr Bijan Heidari

Position

Orthopedist

Other areas of specialty/work**Street address**

Shahid Mobasher Kashani Clinic, Mahdieh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3827 4184

Fax**Email**

dr.bijanheidari80@gmail.com

Web page address**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

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

Hamadan

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***Person responsible for general inquiries****Contact****Name of organization / entity**

School of Pharmacy

Full name of responsible person

Dr Dara Dastan

Position

Pharmacologist

Other areas of specialty/work**Street address**

School of Pharmacy, Hamadan University of Medical

Sciences, Shahid Fahmideh Ave.

City

Hamadan

Postal code**Phone**

+98 81 3838 0572

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

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of

Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code**Phone**

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

Web page address**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