

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the effect of topical application of the combination of Arnica, Aconitum, Atropa belladonna, Calendula officinalis, Hypericum perforatum, Ruta graveolens and Hamamelis in relieving chronic occupational low back pain

Protocol summary

Study aim

Determining the effect of topical application of the combination of Arnica, Aconitum, Atropa belladonna, Calendula officinalis, Hypericum perforatum, Ruta graveolens and Hamamelis in relieving chronic occupational low back pain

Design

Clinical trial with control group, with parallel groups, triple blind, randomized, phase 2-3, 20 patients in each group, randomization with random prescription of one of the packages containing the compounds or placebo.

Settings and conduct

Patients referred to the orthopedic clinic of Shahid Ghazi hospital in Sanandaj, Kurdistan province, will be included in the study according to the inclusion and exclusion criteria. In both groups, patients' demographic information will be recorded and measured by pain intensity using the Visual Analogue Pain Index and disability will be assessed using the Million Visual Analogue Scale and Oswestry questionnaire. In the case group, a combination containing the plants will be prescribed. A placebo will also be prescribed in the control group. The packaging of the compounds in the two groups is coded as A and B and researchers, patients and statistical consultants will not know the contents of the tubes until the end of the study. Patients will be followed up for two months, during which time they will be visited every 14 days.

Participants/Inclusion and exclusion criteria

Patients referred to orthopedic clinic. Inclusion criteria: Diagnosis of chronic occupational low back pain over 18 years of age Exclusion criteria: pregnancy, lactation, taking any analgesic and anti-inflammatory drugs except the studied compounds.

Intervention groups

Including case and control groups: in the case group, 5.2

grams of the herbal combination will be used once every 8 hours, and in the control group, placebo will be prescribed in the same way.

Main outcome variables

Pain intensity; Pain frequency; Disability intensity; Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200913048700N1**

Registration date: **2023-04-15, 1402/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-15, 1402/01/26**

Update count: **0**

Registration date

2023-04-15, 1402/01/26

Registrant information

Name

Seyyed Nima Naleini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3724 9033

Email address

nima.naleini@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01
Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of topical application of the combination of Arnica, Aconitum, Atropa belladonna, Calendula officinalis, Hypericum perforatum, Ruta graveolens and Hamamelis in relieving chronic occupational low back pain

Public title
Evaluation of the effect of topical application of the combination of Arnica, Aconitum, Atropa belladonna, Calendula officinalis, Hypericum perforatum, Ruta graveolens and Hamamelis in relieving chronic occupational low back pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of chronic occupational low back pain Age over 18 years
Exclusion criteria:
Pregnancy Breastfeeding Consumption of any analgesic and anti-inflammatory drugs except the studied compounds

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random, Individual, Random administration of medication / placebo Random allocation: First, 20 envelopes containing the letter A and the same number containing the letter B are prepared, and then without the researcher knowing the contents of each envelope, he will give one envelope to each patient and based on what letter is inside the envelope, they are placed in the case group (letter A) or control group (letter B).

Blinding (investigator's opinion)
Triple blinded

Blinding description
Packaging of the compounds in the two groups is coded

as A and B, and researchers and patients will not know the contents of the cream tubes

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Baqiyatallah Hospital

Street address

South Sheikh Bahaei, Molasadra Ave, Vanak Sq

City

Tehran

Province

Kurdistan

Postal code

1435916471

Approval date

2023-02-20, 1401/12/01

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.122

Health conditions studied

1

Description of health condition studied

Chronic Occupational Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Intensity of pain

Timepoint

0, after two weeks, after a month

Method of measurement

Pain Visual Analog Scale

2

Description

Severity of disability

Timepoint

0, after two weeks, after a month

Method of measurement

Million Visual Analogue Scale and Oswestry disability

3**Description**

Pain Frequency

Timepoint

0, after two weeks, after a month

Method of measurement

Asking the patient

Secondary outcomes**1****Description**

Side Effects

Timepoint

0, after two weeks, after a month

Method of measurement

Asking the patient

Intervention groups**1****Description**

Intervention group: Taking the composition containing the plants (Arni Gol cream) once every 8 hours for 1 month in the amount of two and a half grams

Category

Treatment - Drugs

2**Description**

Control group: Taking placebo with the same form and instructions as the intervention group

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Ghazi Hospital

Full name of responsible person

Seyyed Nima Naleini

Street address

Tarif Ave, Pasdaran Ave

City

Sanandaj

Province

Kurdistan

Postal code

6714435654

Phone

+98 939 864 6820

Email

nimanaleini@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Goldaru Herbal Pharmaceutical Company

Full name of responsible person

Alireza Homayouni

Street address

No. 47, Soffeh Industrial Park, Km 7 of Shiraz Road, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8179135111

Phone

+98 31 3654 1370

Email

info@goldaruco.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Goldaru Herbal Pharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Industry

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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Ghasemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Occupational Medicine

Street address

Sheikh Bahaei Ave, Molasadra Ave, Vanak Sq

City

Tehran

Province

Tehran

Postal code

1435916471

Phone
+98 912 145 2405
Email
mghmed@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad Ghasemi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Occupational Medicine
Street address
Sheikh Bahaei Ave, Molasadra Ave, Vanak Sq
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 912 145 2405
Email
mghmed@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Seyyed Nima Naleini
Position
Medical Doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Shohadaye Nirooie Entezami Blvd, Pasdaran Ave
City
Sanandaj
Province

Kurdistan
Postal code
6617979937
Phone
+98 939 864 6820
Email
nimanaleini@yahoo.com

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

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

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

Title and more details about the data/document

All information is provided upon request by qualified persons

When the data will become available and for how long

After the publication of the study report

To whom data/document is available

Relevant organizations

Under which criteria data/document could be used

It is not possible to reuse data in studies. These data will be provided only to verify the results by relevant organizations such as ethics committees.

From where data/document is obtainable

Correspondence with the authors of the article

What processes are involved for a request to access data/document

The requester writes a letter to the corresponding author of the study and mentions his purpose of using of the documents and sends it to the email address mentioned in the article, and then the request will be seen by the authors and the ethics committee, and if approved, the documents will be sent to him in the shortest possible time (At least two weeks).

Comments