Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of topical application of the combination of Arnica, Aconitum, Atropa belladonn, 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 belladonn, 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 belladonn, 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 belladonn, 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

index

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
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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
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Province
Isfehan
Postal code
۸۱۷۹۱۳۵۱۱۱
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
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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
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