Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of topical chamomile herbal product on the symptoms of patients with leg cramps in comparison with standard treatment: a double-blind clinical trial

Protocol summary

Study aim
Investigating the effect of chamomile topical product on the severity of symptoms of people with muscle cramps

Design
This study is a double-blind randomized clinical trial study with a control group and a parallel design, which is conducted in the third phase of the trial on 64 people with muscle cramps in the leg area.

Settings and conduct
Every person who meets the criteria for entering the study is evaluated by an Iranian medical specialist using the VAS tool in the first visit (before the start of the study) and subsequent visits (after the start of the intervention). They are evaluated daily and up to a score of less than four in the VAS tool. Referrals to the health school of Babol University of Medical Sciences, Rouhani Hospital Clinic are examined. Chamomile product and diclofenac gel in a single form, with the same label and the same smell and color (with the addition of color and essential oil) by a pharmaceutical specialist in the herbal laboratory. Medicines will be prepared by the Faculty of Iranian Medicine in Babol. The only person who knows the nature of drugs is the pharmacist who makes the drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Men and women aged 20 to 60 years 2. Presence of pain with a vas score greater than six Exclusion: 1. Lack of full assessment to monitor the treatment process 2. Lack of satisfaction during treatment 3. The presence of underlying diseases related to cramps

Intervention groups
1. The intervention group includes people with muscle cramps in the leg area who receive topical chamomile products. 2. The comparison group includes people suffering from muscle cramps in the leg area, receiving 1% diclofenac gel.

Main outcome variables
Treatment duration, pain index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200105046009N7**
Registration date: **2023-01-09, 1401/10/19**
Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**
Update count: **0**

Registration date
2023-01-09, 1401/10/19

Registrant information

Name
Seyyed Ali Mozaffarpur

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3219 4728

Email address
dr.mozaffarpur@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-20, 1401/10/30

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical chamomile herbal product on the symptoms of patients with leg cramps in comparison with standard treatment: a double-blind clinical trial

Public title

The effect of topical chamomile herbal product on the symptoms of patients with muscle cramps

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women aged 20 to 60 years Presence of muscle cramp in the gastrocnemius muscle The presence of pain with a vas score greater than six

Exclusion criteria:

Lack of complete evaluation to monitor the treatment process Lack of satisfaction during treatment The presence of underlying diseases related to cramps Using other painkillers Performing procedures that lead to the improvement of muscle cramps History of recurrent cramps without clear cause

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using the permuted block randomization method. The size of the blocks is 4 and the ratio of drug to control (diclofenac gel) in each group is equal to (1:1). In each block, random permutations of 4 combinations of chamomile formulation and diclofenac gel are considered. Random sequence generation will be done by the design methodologist. In order to hide the treatment process, random codes are written on the boxes containing medicine (chamomile product/diclofenac) and after assigning the medicine to the patients, the corresponding code is recorded on the patients' files. The opening of the codes will be done after the end of the study. In case of side effects, the code of that medicine will be opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

Chamomile product and diclofenac gel in a single form, with the same label and the same smell and color (with the addition of color and essential oil) will be prepared by a pharmaceutical specialist in the medicinal plant laboratory of the Faculty of Iranian Medicine in Babol. The only person who knows the nature of drugs is the pharmacist who makes the drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Babol University of Medical sciences, Sargord Ghasemi avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4718647745

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.205

Health conditions studied

1

Description of health condition studied

muscle cramp

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

Primary outcomes

1

Description

pain index

Timepoint

The VAS measurement is measured before the intervention and on even days after the start of the intervention, and the treatment continues until the pain index reaches 4 or a change of 1.7 based on the MCID.

Method of measurement

Pain intensity measurement using VAS tool

2

Description
Duration of treatment
Timepoint
VAS is measured before the intervention and on even days after the start of the intervention, and the examination of the pain index continues until the day it reaches the number 4 or the change rate of 1.7 based on the MCID.
Method of measurement
Pain intensity measurement using VAS tool

Secondary outcomes

1

Description
redness
Timepoint
Measurements are taken before the intervention and on even days after the start of the intervention, and the treatment continues until the pain index reaches 4 or a change of 1.7 based on the MCID.
Method of measurement
By patient report or evaluator observation

2

Description
Itching
Timepoint
Measurements are taken before the intervention and on even days after the start of the intervention, and the treatment continues until the pain index reaches 4 or a change of 1.7 based on the MCID.
Method of measurement
By patient report or evaluator observation

3

Description
swelling
Timepoint
Measurements are taken before the intervention and on even days after the start of the intervention, and the treatment continues until the pain index reaches 4 or a change of 1.7 based on the MCID.
Method of measurement
By patient report or evaluator observation

Intervention groups

1

Description
Chamomile topical product (combination of chamomile oil and wax made in the laboratory of the Iranian Faculty of Medicine) in the amount of one knuckle every eight hours is used topically on the leg muscles and the VAS index, before the intervention and on even days after The start of the intervention is measured and the treatment continues until the pain index reaches 4 or a change of 1.7 based on the MCID.
Category
Treatment - Drugs

2

Description
1% diclofenac gel of Soban company is used topically on the calf muscles in the amount of one knuckle every eight hours, and the VAS index is measured before the intervention and on even days after the intervention, and the treatment is continued until the day the pain index is reached. Continued to number 4 or a rate of change of 1.7 based on MCID
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roohani Hospital
Full name of responsible person
Seyyed Ali Mozaffarpur
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2

Recruitment center
Name of recruitment center
Health College of Iranian Medicine, Babol University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Babol 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
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Full name of responsible person
Seyyed Ali Mozaffarpur
Position
Associate Professor
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

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

Comments