

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the analgesic effects of Topical application Althaea officinalis ointment and Piroxicam gel in patients with chronic low back pain

Protocol summary

Study aim

Comparison of the analgesic effects of topical application Althaea officinalis ointment and Piroxicam gel in patients with chronic low back pain

Design

This study is a clinical trial with parallel groups, double blind, randomized, phase 3 on 110 patients

Settings and conduct

Among the people referring to the medical centers of Fasa University of Medical Sciences, people who suffer from chronic non-specific low back pain based on clinical evaluation and doctor's approval are included in the study after obtaining informed consent. 110 patients with chronic low back pain are purposefully selected and randomly divided into 2 groups of 55 people. One group receives Althaea officinalis ointment and the other group receives Piroxicam gel. The drugs are given to patients in coded containers and without names. This is a double-blind clinical trial (outcome assessor-patients)

Participants/Inclusion and exclusion criteria

Patient informed consent; doctor's approval; back pain for more than three months; pain intensity higher than 3 on the Visual Analogue Scale; score higher than 4 in the Roland-Morris Disability Questionnaire

Intervention groups

Intervention group 1: 2.5 gr of Althaea officinalis ointment used topically twice a day for each person and Acetaminophen 500 mg tablets once a day for 14 days
Intervention group 2: 2 gr of 0.5% Piroxicam gel, which is used twice a day for each person and Acetaminophen 500 mg tablets once a day for 14 days

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050387N1**

Registration date: **2021-03-27, 1400/01/07**

Registration timing: **prospective**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

Registration date

2021-03-27, 1400/01/07

Registrant information

Name

Maryam Kianitabar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effects of Topical

application Althaea officinalis ointment and Piroxicam gel in patients with chronic low back pain		Secondary Ids
		empty
Public title	Evaluation of the effect of Althaea officinalis ointment in chronic low back pain relief	Ethics committees
Purpose	Treatment	1
Inclusion/Exclusion criteria		Ethics committee
Inclusion criteria:	Patient informed consent Doctor's approval Back pain for more than three months Pain intensity higher than 3 on the Visual Analogue Scale Score higher than 4 in the Roland-Morris Disability Questionnaire	Name of ethics committee
Exclusion criteria:	Having surgery, fractures, dislocations and sprains in the spine Diseases such as osteoporosis, osteoarthritis, cancer, rheumatism, disc herniation, sciatica, inflammatory diseases, malignant tumors Nervous system diseases and spinal cord injuries Skeletal malformation Severe structural disorder of the lower limbs and spine Pregnancy Injectable analgesics and corticosteroids	Ethics committee of Fasa University of Medical Sciences
Age	From 20 years old	Street address
Gender	Both	Avicenna square, Fasa University of Medical Sciences
Phase	3	City
Groups that have been masked		Fasa
	- Participant - Outcome assessor	Province
Sample size	Target sample size: 110	Fars
Randomization (investigator's opinion)	Randomized	Postal code
Randomization description	A 2 groups will be studied and each of the letters A and B will be assigned to an intervention group, 6 possible modes for placing the letters A and B in will be considered in blocks of 4. 28 blocks of 4 will be considered. For concealment, the type of intervention is written in a random allocation sequence, placed in opaque sealed envelopes and are encoded on the envelopes in order.	7461686688
Blinding (investigator's opinion)	Double blinded	Approval date
Blinding description	patients randomly divided into 2 groups of 55 people. One group receives Althaea officinalis ointment and the other group receives Piroxicam gel. The drugs are given to patients in coded containers and without names. This is a double-blind clinical trial (outcome assessor-patients)	2021-03-02, 1399/12/12
Placebo	Not used	Ethics committee reference number
Assignment	Parallel	IR.FUMS.REC.1399.176
Other design features		Health conditions studied
		1
		Description of health condition studied
		low back pain
		ICD-10 code
		M54.5
		ICD-10 code description
		Low back pain
		Primary outcomes
		1
		Description
		Pain intensity
		Timepoint
		Beginning of the intervention - end of the intervention and 2 weeks after the end of the intervention
		Method of measurement
		Visual Analogue Scale
		Secondary outcomes
		1
		Description
		Functional Disability
		Timepoint
		Before intervention - end of the intervention
		Method of measurement
		Roland-Morris Disability Questionnaire
		2
		Description

Blood pressure
Timepoint
Before intervention - end of the intervention
Method of measurement
Aneroid Sphygmomanometer

3

Description
Oxygen saturation
Timepoint
Before intervention - end of the intervention
Method of measurement
Finger Pulse Oximeter

4

Description
Pulse rate
Timepoint
Before intervention - end of the intervention
Method of measurement
Finger Pulse Oximeter

5

Description
Respiratory rate
Timepoint
Before intervention - end of the intervention
Method of measurement
Stopwatch

Intervention groups

1

Description
Intervention group: 2.5 gr of 20% Althaea officinalis ointment produced in the laboratory of medicinal plants of Fasa University of Medical Sciences used topically twice a day for each person and Acetaminophen 500 mg tablets (manufactured by Zagros darou) once a day for 14 days.
Category
Treatment - Drugs

2

Description
Intervention group: 2 gr of 0.5% Piroxicam gel(manufactured by Razk laboratories), which is used twice a day for each person topically, and Acetaminophen 500 mg tablets(manufactured by Zagros darou) once a day for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical centers of Fasa University of Medical Sciences
Full name of responsible person
Maryam Kianitabar
Street address
Medical centers of Fasa University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr. Mojtaba Farjam
Street address
Avicenna square, Fasa University of Medical Sciences
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Email
research@fums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa 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

L.nikrouz@fums.ac.ir

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Leila Nikrouz

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Full name of responsible person

Maryam Kianitabar

Position

Master student of Medical Surgical Nursing

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Bachelor

Other areas of specialty/work

Nursery

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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