

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of Linum album on restoration of distal radius bone fracture

Protocol summary

Study aim

The effect of Linum album as an ointment on the repair of distal radius bone fractures

Design

This study is a clinical trial. In this study, there are two control groups (placebo) and the intervention group (Linum album ointment). How to divide randomly is simple. The number of subjects in each group is 30. This is a double-blind study in which statistical analysts and participants are unaware of data and drugs.

Settings and conduct

The study site is Arak University of Medical Sciences and Valiasr Hospital. First, patients with distal radius fracture are pinned, then splinting is done with Linum album ointment. In the control group, splinting is performed with placebo. Patients are examined ten days after splinting to assess pain and swelling at the site. Simultaneously with the first ten days of examination, routine X-rays are performed on patients and while using the second administration of Linum album ointment, splinting is performed simultaneously. This process is done every 10 days for a month.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: "Having informed consent to participate in the study, definitive diagnosis of distal radius bone fractures and not attending in another clinical trial." exclusion criteria include: "Patient willingness to accept other therapies

Intervention groups

Drug group: Ointment prepared on the basis of Linum album plant, which is produced with a concentration of 10% Linum album extract, is prescribed once every 10 days for a month. This Ointment is made by the Research Center of Traditional and Complementary Medicine of Arak University of Medical Sciences. Control group: Consumes a placebo that will be just a gel based on Carbomer 934 with the same color and packaging.

Main outcome variables

Recovery time, pain, inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180610040049N7**

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

Amirhosein Latifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-07, 1400/01/18

Expected recruitment end date

2021-06-08, 1400/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Linum album on restoration of distal radius bone fracture

Public title
The effect of Linum album on restoration of bone fracture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent to participate in the study
The definitive diagnosis of distal radius bone fracture
Failure to attend another clinical trial simultaneously
Exclusion criteria:
Patient's willingness to use other therapies
Menopausal women

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study is a simple randomized clinical trial on people with distal radius fractures. . In this study, simple randomization method will be used. A randomized list will be generated by online randomization site (sealedenvelope.com). Individuals will be allocated to intervention or control group according to the list.

Blinding (investigator's opinion)
Double blinded

Blinding description
The intervention group is given an herbal product as an ointment and the other group is given a placebo. Statistical analyzer and participant are not given information about the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address

Arak University of Medical Sciences,Basij Square

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2021-01-23, 1399/11/04

Ethics committee reference number
IR.ARAKMU.REC.1399.302

Health conditions studied

1

Description of health condition studied
Distal radius bone fracture

ICD-10 code
M96.63

ICD-10 code description
Fracture of radius or ulna following insertion of orthopedic implant, joint prosthesis, or bone plate

Primary outcomes

1

Description
Recovery time

Timepoint
Once every 10 days for a month

Method of measurement
Using bone imaging

2

Description
Pain

Timepoint
Once every 10 days for a month

Method of measurement
Using a VAS questionnaire

Secondary outcomes
empty

Intervention groups

1

Description
"Intervention group:" This group uses Linum album ointment. The concentration of this ointment is 10% of aqueous extract of Linum album. It is administered topically for 10 days once a month. This ointment is made by Shahid Beheshti School of Pharmacy and Arak University of Medical Sciences Traditional and Complementary Medicine Research Center.

Category
Treatment - Drugs

2

Description

"Control group:" This group uses placebo ointment. This ointment is based on 934 carbomer. It is administered topically for 10 days once a month. This ointment is made by Shahid Beheshti School of Pharmacy and Arak University of Medical Sciences Traditional and Complementary Medicine Research Center.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Valiasr Hospital

Full name of responsible person

Mehran Azami

Street address

Valiasr Hospital, Imam St, Arak

City

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3848176341

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Seied Amirhosein Latifi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Arak University of Medical Sciences

Full name of responsible person

Faezeh Amirpour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable