Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Valiasr Hospital, Imam St, Arak
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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
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Arak University of Medical Sciences, Basij Square, Arak
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Alireza Kamali
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research@arakmu.ac.ir
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
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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Faezeh Amirpour

Position

Student

Latest degree

Bachelor

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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