

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effect of the Drug "Mumiaee" on the Union Period of Distal Radius Fractures: A Randomized Clinical Trial

Protocol summary

Study aim

Effect of the drug "Mumiaee" on the union duration of distal radius fractures.

Design

A two armed, randomized, superiority, parallel group clinical trial; triple-blind, in phase 2 and 3 over a group of 44 patients. Randomization is done via the software: Random Allocation.

Settings and conduct

This study is conducted on patients referred to the clinic and ward of Orthopedic Surgery in Imam Reza Hospital in Mashhad. 44 patients after informed consent and receiving the primary care will be divided into 2 arms. The intervention arm will receive 4 capsules, containing the drug Mumiaee (Shilajit) and the control arm will receive 4 capsules containing the substance Avisel (Placebo) daily for 1 month. All patients will receive a follow-up every 2 weeks including: a wrist x-ray, Physical Examinations and 3 questionnaires on week 6 and 12. The participants, the researchers including: the treating physician, the data collector and the assessor of the results will be blinded.

Participants/Inclusion and exclusion criteria

Patients in the age group of 18 to 80 years old with externally fixed distal radius fractures will be included; Patients with pathological fractures and underlying bone diseases or past medical histories such as Diabetes, Rheumatoid Disease or immune deficiencies that may delay the union will not be included.

Intervention groups

Intervention arm of the study will receive 4 capsules, containing the drug Mumiaee (Shilajit), as a supplement besides their primary care, daily for 1 month. The control arm will receive 4 capsules containing the substance Avisel (Placebo), besides the primary care, daily for 1 month.

Main outcome variables

Period of union; Range of motion of the wrist; Grip Strength; Wrist function evaluation by PRWE

questionnaire; Upper limb activity evaluation by QDASH questionnaire; Evaluation of pain by VAS questionnaire.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191216045758N1**

Registration date: **2020-10-21, 1399/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-21, 1399/07/30**

Update count: **0**

Registration date

2020-10-21, 1399/07/30

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2021-10-06, 1400/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of the Drug "Mumiaee" on the Union Period of Distal Radius Fractures: A Randomized Clinical Trial

Public title

Evaluation of the Effect of the Drug "Mumiaee" on the Union Period of Distal Radius Fractures

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Closed Fractures Fernandez Fractures type 1-3 that are fixed by PCP or External Fixators. Lack of Rheumatoid Disease, Diabetes and Immune Deficiency in the past medical history of the participants.

Exclusion criteria:

Pathological Fractures Underlying Bones Diseases such as Osteopetrosis Unexpected Special Medical Conditions

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method of this clinical trial is "Blocked". The type of this research is "Superiority" and is evaluated via "Parallel" method. By using Random Allocation Software, random blocks ,with variable sizes of 4 and 6, containing equal number of each group are designed. The arrangement of contents in each block ensures the equilibrium allocation of individuals in the study groups. By patients' visits, one of the blocks is randomly chosen (via shuffling) and the patients are assigned to the groups of the study based on the content order of the block. Whenever the contents of the block, based on its size, are finished, a new block will be randomly chosen to cover the other patients and this process is repeated until all the patients are assigned to groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the participants and the principle researcher (the treating physician), the researcher responsible for collecting the data and the assessors of the results are blinded. The final analyzers of data, the ones writing the final article and Data Safety and

Monitoring Committee are not blinded. In order to blind the study, a person who is not involved in the study, will randomly open a block by each patient visit and will draw a card based on the order of content of the block and give it to the patient. These cards are coded by color into groups A and B. One of the researchers of the study who is not blinded will later give the drug or the placebo to the patients based on the codes assigned. Therefore this study is three way blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Medicine Faculty, Ferdowsi University of Mashhad, Azadi Square.

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Province

Razavi Khorasan

Postal code

9177948564

Approval date

2020-08-11, 1399/05/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.330

Health conditions studied**1****Description of health condition studied**

Distal Right Radius Fracture

ICD-10 code

S52.501A

ICD-10 code description

Unspecified fracture of the lower end of right radius, initial encounter for closed fracture

2**Description of health condition studied**

Distal Left Radius Fracture

ICD-10 code

S52.502A

ICD-10 code description

Unspecified fracture of the lower end of left radius, initial encounter for closed fracture

Primary outcomes

1

Description

Union Period of Distal Radius Fracture

Timepoint

At the beginning of the study and on the weeks 2, 4, 6, 8, 10, 12.

Method of measurement

Wrist X-Ray

Secondary outcomes

1

Description

Wrist Range of Motion

Timepoint

On the weeks: 2, 4, 6, 8, 10 and 12.

Method of measurement

By using Goniometer

2

Description

Wrist Pain and Disability in Activities of Daily Living

Timepoint

After the initial treatment and the start of Mumiaee (Shilajit) consumption on the weeks 6 and 12.

Method of measurement

By using Patient-Rated Wrist Evaluation questionnaire.

3

Description

Physical Function of Upper Limb

Timepoint

At the start of Mumiaee (Shilajit) consumption on the weeks 6 and 12.

Method of measurement

By using Quick Disabilities of Arm, Shoulder and Hand questionnaire.

4

Description

Patient's Wrist Pain

Timepoint

At the start of Mumiaee (Shilajit) consumption on the weeks 6 and 12.

Method of measurement

By Visual Analog Scale Pain questionnaire.

5

Description

Hand Grip Strength

Timepoint

After the initial treatment and the start of Mumiaee (Shilajit) consumption on the weeks 6 and 12.

Method of measurement

By Orthopedic Equipment Dynamometer

Intervention groups

1

Description

Intervention group: consists of 22 patients who will receive 4 capsules of Mumiaee (Shilajit) containing 250 mg of the substance (a total of 1000 mg per day) every 6 hours, daily for 1 month. This medicine is produced in Pharmacological Herbs Research Institute of Mashhad University of Medical Sciences. Mumiaee (Shilajit) has been commonly used in tradition medicine over the years. This substance consists of Amino Acids, Albuminoids, Fatty Resinoic Acids, Benzoic Acid, Hippuric Acid. The most important substance in this medicine is Fulvic Acid which has anti-inflammatory and anti-oxidant effects. Mumiaee also contains mineral such as Copper, Magnesium, Calcium, Manganese, Nickel, Iron, Zinc, Lithium and Molybdenum.

Category

Treatment - Other

2

Description

Control group: consists of 22 Patients who will receive 4 placebo capsules, containing 100 mg of Avisel Powder, every 6 hours daily for 1 month. Avisel Powder consists of Microcrystalline Cellulose.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ali Moradi

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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
Mashhad 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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data potentially can be shared after anonymization of the participants.

When the data will become available and for how long

Data access allowed 6 months after publication of the research

To whom data/document is available

Researchers working in academic and scientific institutes

Under which criteria data/document could be used

With the permission of the author, there is no problem with using the documentation.

From where data/document is obtainable

Kimia Emami Email: kimia.emami.96@gmail.com Dr. Ali Moradi (MD, PhD) Email: almor0012@gmail.com

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

The document can be sent in less than one month via email.

Comments