Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Acacia Arabica as an adjuant therapy with placebo in healing of the distal radius bone fracture

Protocol summary

Summary

This is an interventional study that evaluates the effect of oral Arabic Gum compared with placebo on the union fractures of the distal radius bone. The focus group includes adults with age 20-60 consciously selected and randomly divided into intervention and control groups. Besides conventional orthopedic treatment (replacement and fixation by plaster) for each patient, the supplement and placebo will be prescribed at the 8th day after the fracture for a duration of 21 days. The intervention group will take Arabic Gum powder and the control group will take dried bread powder as placebo. Radiologic Union Score System (callus formation and disappearance of fracture line) will be evaluated in both intervention and control groups in the third, fourth and sixth weeks after the fracture by two orthopedic specialists. Simple plain and lateral wrist x ray roentgenography are the choice Radio-graphic tests. Clinical criteria for healing based on Numeric Rating Scale System (hyperalgesia and active and passive wrist movement quality) will be evaluated at the sixth week (at the time of opening of plaster).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040327196N1**
Registration date: **2017-07-12, 1396/04/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

Farshad Amini Behbahani

Name of organization / entity

School of Traditional Medicine, Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

1- Vice chancellor for research, Iran University of Medical Sciences 2- Research Institute for Islamic and Complementary Medicine, Iran University of Medical Sciences

Expected recruitment start date

2017-06-09, 1396/03/19

Expected recruitment end date

2018-06-09, 1397/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Acacia Arabica as an adjuant therapy with placebo in healing of the distal radius bone fracture

Public title

The effect of Arabic gum on radius fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Distal radius bone fractures with displacement (type A of AO Classification) Exclusion criteria: partial or complete intra-articular fractures. (Type B and C category AO); multi-piece fractures (Type

C classification AO); fractures with internal or external fixation management criteria; Bilateral fractures or presence of fractures in the other bones (except distal radius and ulnar); initiation of treatment 24 hours or more after the fracture; association of vascular or nervous complications; Multiple Trauma; open fracture; History of previous fracture in the same position; fracture with dislocation of the wrist bones; pathological fractures; Chronic diseases such as diabetes, cancer, auto immune diseases, inflammatory kidney diseases, coronary heart diseases or advanced pulmonary diseases; decreased consciousness; pregnancy or lactation; alcohol addiction; tobacco or drug addiction; allergies to herbal medicines.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences Ethics Committee

Street address
Iran University of medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Postal code
1449614535

Approval date
2016-01-17, 1394/10/27

Ethics committee reference number
IR.IUMS.REC.1394.8911558006

Health conditions studied

1

Description of health condition studied
Distal fracture of radius bone

ICD-10 code
S52.5

ICD-10 code description
Fracture of lower end of radius

Primary outcomes

1

Description
Callus formation and disappearance of fracture line

Timepoint
Week 3 and 4 and 6

Method of measurement
radiography

Secondary outcomes

1

Description
Pain assessment at the touch position and active/passive movement of fractured wrist

Timepoint
At the end of the sixth week after the opening of plaster

Method of measurement
Numeric Rating 11-point scale

Intervention groups

1

Description
Intervention group: replacement + plaster + follow-up radiographies and visits by Orthopedist + 500 mg Arabic Gum capsule twice daily (at the morning and evening) for 21 days duration.

Category
Treatment - Drugs

2

Description
Control group: replacement + plaster + follow-up radiographies and visits by Orthopedist + 500 mg dried bread powder capsule twice daily (at the morning and evening) for 21 days duration.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Dr Moayeri Hospital

Full name of responsible person

Masood Hatami

Street address

Shahid Dr Moayeri Hospital, in front of Parliament, Mojahedin e Islam street, Shohada Square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

,Iran University of Medical Sciences ,Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary Medicine, Iran University of Medical Sciences

Full name of responsible person

Fataneh Hashem Dabaghian

Street address

No. 9, Pirnia alley, Lalezar Now Ave., Jomhouri Eslami St., Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Institute for Islamic and Complementary Medicine, Iran University of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Institute for Islamic and Complementary Medicine, School of Iranian Traditional Medicine, I

Full name of responsible person

Masood Hatami

Position

PhD candidate of traditional medicine MD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Traditional Medicine MD-PhD/ Head of of Traditional Medicine Department

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty