

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparing effect of oral Mummy drug (Mountain Sweat) with placebo in healing time of tibia bone shaft fracture in adult men

Protocol summary

Summary

A- Study population: Patients with tibia bone shaft fracture who admit to the Akhtar Hospital. Study objectives: To assess the effect of oral mummy drug (Mountain Sweat) on union time of tibia bone shaft fracture in adult patients admitting to Akhtar Hospital in 2014. Study Design: Randomized, double-blind, placebo-controlled, single-center, phase II clinical trial. Main inclusion criteria: 1. The male gender 2. Fracture of tibia bone shaft 3. Less than 10 days from the time of fracture to initiation of intervention 4. Age between 18 and 50 Main exclusion criteria: 1. Orthopedic complication that prevents the continuation of the research process (in consultation with orthopedic surgeon and researcher) 2. Taking medications that affecting the bone repair 3. Surgery again 4. Pathological fracture 5. Underlying disease affecting the recovery process of fractures of the bone (immunodeficiency, tumor, osteoporosis, liver or renal failure) 6. Addiction B- The study intervention or interventions: Administration of oral mummy drug (1 gram per day) or placebo (Wheat flour) to patients in capsule form C- Intervention duration: 28 days D- The primary outcome or outcomes studied: Acceleration of the fracture union

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052013389N1**
Registration date: **2014-01-19, 1392/10/29**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-19, 1392/10/29

Registrant information

Name

Sayed Mohammad Hassan Sadeghi

Name of organization / entity

School of Traditional Medicine, Shahid Behe

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3522

Email address

smhsadeghi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Government sources

Expected recruitment start date

2014-02-22, 1392/12/03

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of oral Mummy drug (Mountain Sweat) with placebo in healing time of tibia bone shaft fracture in adult men

Public title

The effect of oral mummy drug on bone fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. The male gender 2. Fracture of tibia bone shaft 3. Initiation of intervention in less than 10 days from the time of fracture 4. Age between 18 and 50 5. Completing the consent form Exclusion criteria: 1.

Orthopedic complication that prevents the continuation of the research process (in consultation with orthopedic surgeon and researcher) 2. The unpredictable complications leading to intolerance of medication or placebo such as idiosyncratic complications (in consultation with orthopedic surgeon and researcher) 3. Taking medications that affecting the bone repair 4. Surgery again 5. Pathological fracture 6. Underlying disease affecting the recovery process of fractures of the bone (immunodeficiency, tumor, osteoporosis, liver or renal failure) 7. Addiction 8. Severe infection of the bone or tissue around the location of the fracture or damage of the artery (according to the criteria of the Gustillo-Anderson 3C or 3B)

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Drug and placebo will be prepared in the same form of capsule and packaging. Then they will be coded by a third person. After matching intervention and control groups with respect to the type of fracture, they will take drug and placebo randomly. Consequently the patients and researcher are not notified of the group assigned until the end of the study.

Secondary Ids

empty

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

Ethics committee of Shahid Beheshti University of Medical Science

Street address

Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh St., Yemen St., Shahid Chamran Highway

City

Tehran

Postal code**Approval date**

2013-09-14, 1392/06/23

Ethics committee reference number

400/4014

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

Tibia bone shaft fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes**1****Description**

Union time of tibia bone shaft fracture

Timepoint

Two, four, six, eight, ten and twelve weeks after the start of the intervention

Method of measurement

Swiss-ray digital radiology device

Secondary outcomes**1****Description**

Side effects

Timepoint

Two, four, six, eight, ten and twelve weeks after the start of the intervention

Method of measurement

Questionnaire

Intervention groups**1****Description**

Administration of oral mummy drug, daily total of four capsules, for 4 weeks, each capsule contains 250 mg of oral mummy drug. It should be taken with water one hour before or three hours after meals.

Category

Treatment - Drugs

2**Description**

Administration of Golha wheat flour (0000) in form of edible capsules similar to the packaging of oral mummy drug, a total of four capsules daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Sayed Mohammad Hassan Sadeghi, Ph.D. student of Traditional Medicine

Street address

Azar Deadlock, Sharifi-manesh St., Pole-Rume St., Shariati Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

No. 8, Shams Alley, Vali Asr St.

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, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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**

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sayed Mohammad Hassan Sadeghi

Position

Ph.D. student of Traditional Medicine

Other areas of specialty/work**Street address**

No. 8, Shams Alley, Vali Asr St.

City

Tehran

Postal code**Phone**

+98 21 8877 3521

Fax**Email**

Dr.smhs@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sayed Mohammad Hassan Sadeghi

Position

Ph.D. student of Traditional Medicine

Other areas of specialty/work**Street address**

No. 8, Shams Alley, opposite, Vali Asr St.

City

Tehran

Postal code**Phone**

+98 21 8877 3521

Fax**Email**

Dr.smhs@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

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Dr.smhs@yahoo.com

Web page address

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