

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of the use of bone stabilizer and non-use of bone stabilizer for bone fracture in patients with bone fracture to accelerate and improve surgery.

Protocol summary

Study aim

Comparison of the use of bone stabilizer and non-use of bone stabilizer for bone fracture in patients with bone fracture to accelerate and improve surgery.

Design

In this study, patients with high bone fracture are divided into two groups of control and intervention. In this study, the participants do not know how to allocate to the group and the study is one-way blind. The number of participants in the study is 5 in each group. The method of assigning people in each group is non-random. .
Intervention group: In this group, bone stabilization is used during surgery Control group: In this group, bone stabilizer is not used during surgery. This study is conducted in 2019. The phase of the clinical trial is 1-2.

Settings and conduct

This study is carried out at Arak University of Medical Sciences in Vali Asr . Patients referred to this center who have long bone fractures are divided into two groups of control and intervention. In this study, participants were blind and unaware of the use of stabilizers and their lack of use.

Participants/Inclusion and exclusion criteria

Having a long bone fracture

Intervention groups

Intervention group: In this group, bone stabilization is used during surgery Control group: In this group, bone stabilizer is not used during surgery

Main outcome variables

Disruptions during the Dream

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190113042338N1**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Hamed Rohi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3504

Email address

hamedrohi5304@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-31, 1397/11/11

Expected recruitment end date

2019-06-24, 1398/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the use of bone stabilizer and non-use of bone stabilizer for bone fracture in patients with bone fracture to accelerate and improve surgery.

Public title

Investigating the use of bone stabilizer in bone fracture surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Fracture of tall bones of the leg Bone fracture is less than two days Fractures at one point of each tall bone Satisfaction to enter the study

Exclusion criteria:

Complete bone fracture Small bone fracture

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: 5

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient is unaware of the type of division in the groups.

Placebo

Not used

Assignment

Other

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, Arak, Iran

City

Arak

Province

Markazi

Postal code

38481-7-6941

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.ARAKMU.REC.1397.236

Health conditions studied

1

Description of health condition studied

Fracher tall bone

ICD-10 code

M48.5 Coll

ICD-10 code description

XIII Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description

Disruptions during the Dream

Timepoint

A week later of intervention

Method of measurement

Self-made questionnaire

Secondary outcomes

1

Description

Surgeon satisfaction in using the fixator and lack of use of the fixator

Timepoint

After surgery

Method of measurement

Questionnaire

2

Description

Satisfaction or dissatisfaction of the patient with the operation in two groups

Timepoint

A week later

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: In this group, bone stabilization is used during surgery. This stabilizer fixes during the operation on the bone, which prevents bone movement during drills and surgery, instead of human labor.

Category

Treatment - Devices

2

Description

Control group: In this group, bone stabilizer is not used during surgery. In these patients, the stabilizer is not

used during bone surgery, and instead of manpower is used to fix the bone during drill and surgery.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Medical Education Center, Arak, Iran

Full name of responsible person

Hamed Roohi

Street address

Basij square

City

ARAK

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3504

Fax

+98 56 3417 3524

Email

hamedrohi5304@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmand Zadegan

Street address

Basij square

City

ARAK

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3504

Fax

+98 86 3417 3521

Email

mmatinam81@yahoo.com

Grant name

Grant code / Reference number

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

Yes

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

Hamed Rohi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Basij square

City

ARAK

Province

Markazi

Postal code

3848176941

Phone

008986341735.4

Email

hamedrohi5304@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hamed Rohi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Basij square

City

ARAK

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3504

Email

hamedrohi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hamed Rohi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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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

Not applicable

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Potential data can be shared after being unidentifiable

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

For all who are in the medical group

Under which criteria data/document could be used

There are no specific conditions for access

From where data/document is obtainable

They can use the publication

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

You can ask the person via email

Comments