

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of early weight-bearing and mobilization on the outcomes of patients with unstable ankle fractures after internal fixation surgery

Protocol summary

Study aim

Evaluation of the effect of early weight-bearing and mobilization following internal fixation surgery of unstable ankle fractures

Design

Clinical trial with control group, with parallel groups, not blinded, randomized, phase 3 on 50 patients

Settings and conduct

A total of 50 patients with unstable ankle fracture referred to Shahid Beheshti Hospital in Kashan will be included in this clinical trial. After measuring anthropometric indices, they will be randomly allocated to early weight-bearing/mobilization group or control group and outcomes will be evaluated 2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who aged 18-65 Years, Unstable fractures of lateral malleolus with or without talar shift, Unstable fractures of medial malleolus or vertical fractures of the medial malleolus, Bimalleolar fractures, Trimalleolar fractures (fractures involved less than 25% of posterior malleolus and do not require posterior malleolus surgery), Closed fractures and open fractures of grade 1 and 2. Exclusion criteria: Immature skeleton, Previous ankle surgery, The need for medical care preventing other practical interventions, Impossibility to follow the protocol after the operation, Surgery after more than 14 days from the time of injury, Concurrent posterior malleolus fracture with more than 25% involvement, Grade 3 open fractures, Concurrent Syndesmosis Injury

Intervention groups

Intervention group: Weight-bearing and mobilization will begin 2 weeks after internal fixation surgery of unstable ankle fractures (n = 25) Control group: Weight-bearing and mobilization will begin 6 weeks after internal fixation surgery of unstable ankle fractures (n = 25)

Main outcome variables

Time required to return to work, Time required to bear

full body weight, Olerud-Molander Ankle Score, Number of required physiotherapy sessions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201124049484N1**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **prospective**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Mohammadhadi Mollaabbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

mollaabbasi-mh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-09, 1399/10/20

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of early weight-bearing and mobilization on the outcomes of patients with unstable ankle fractures after internal fixation surgery

Public title

The effects of early weight-bearing and mobilization after internal fixation of unstable ankle fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who aged 18 to 65 Years Unstable fractures of lateral malleolus with or without talar shift Unstable fractures of the medial malleolus or vertical fractures of the medial malleolus Bimalleolar fractures Trimalleolar fractures (fractures involved less than 25% of posterior malleolus and do not require posterior malleolus surgery) Closed fractures and open fractures of grade 1 and grade 2

Exclusion criteria:

Immature skeleton Previous ankle surgery The need for medical care preventing other practical interventions Impossibility to follow the protocol after the operation Surgery after more than 14 days from the time of injury Concurrent posterior malleolus fracture with involvement of more than 25% Open grade 3 fractures Concurrent Syndesmosis Injury

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

First, the intervention group (early weight-bearing) was coded with the letter A and the control group with the letter B, and then using the website www.sealedenvelope.com/simple-randomiser/v1/lists, randomization list was prepared by selecting a sample size of 52 (two groups of 26) and permuted block randomization method (block size=4) (13 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups A or B (Based on the entry order). For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B and the same will continue until the last sample (52th person).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Pezeshk Boulevard, Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2020-11-11, 1399/08/21

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.143

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

Unstable ankle fracture

ICD-10 code

S82

ICD-10 code description

Fracture of lower leg, including ankle

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

Time required to return to work

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Checklist

2**Description**

The time required to bear the full body weight

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Checklist

3**Description**

Olerud-Molander Ankle Score

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Olerud-Molander Ankle Score Checklist

4**Description**

Time required for physiotherapy

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

By asking patients

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

Wound complications (Delay in healing, infection and etc)

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Physical examination

2**Description**

Need for reoperation

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Checklist

3**Description**

Incidence of nonunion

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Plain radiography (X-ray)

4**Description**

Incidence of malunion

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Plain radiography (X-ray)

5**Description**

Range of motion in ankle joint

Timepoint

2 weeks, 6 weeks, 3 months, 6 months and 1 year after surgery

Method of measurement

Physical examination

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

Intervention group: In this group, weight-bearing and mobilization will begin 2 weeks after internal fixation surgery of the ankle fracture (early weight-bearing and mobilization) (n = 25)

Category

Rehabilitation

2**Description**

Control group: In this group, 6 weeks after internal fixation surgery of the ankle fracture, weight-bearing and mobilization will begin (n = 25)

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Davood Dehghani Ashkezari

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Shahid Beheshti Hospital, Ghotbe Ravandi Boulevard, Kashan

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Phone

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Web page address**Sponsors / Funding sources**

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafsheh

Street address

Kashan University of Medical Sciences, Pezeshk
Boulevard, Ghotbe Ravandi Boulevard, Kashan

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Davood Dehghani Ashkezari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Name of organization / entity

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammadhadi Mollaabbasi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available