

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of the immobilization results of lower extremity injuries with two method of short leg standard Splint and half length standard Splint

Protocol summary

Study aim

A comparison of the immobilization results of lower extremity injuries with two method of short leg standard Splint and half length standard Splint

Design

This research will be done by randomized clinical trial. All of the patients who come to the emergency department of "Tehran 7tir Hospital" with trauma to the leg and ankle that need short leg standard splint, will be enroll in this study. Patients will be randomly assigned to two groups by a random block method. Each block contains 10 numbers. Because we did not find any record or research about this subject, a pilot study with 50 patients will be initially performed and corresponding indicators will be derived and based on that sample size calculations will be done using Altman's nomogram.

Settings and conduct

All of the patients who come to the emergency department of "Tehran 7tir Hospital" with trauma to the leg and ankle that need short leg standard splint without any evidence of fracture or dislocation and laceration, will be enroll in this study. Patients will be randomly assigned to two groups. In case group bracing up will be done by using half size splint (from the toes until middle of the leg) and in the control group it will be done by using a regular splint (from the toes until 4 cm below the knee). General information and medical prescription and same advice are implemented for both groups. The pain score of all patients are obtained and recorded for later investigations. After data gathering, Patient's data will be analyzed by person who is blinded to two groups.

Participants/Inclusion and exclusion criteria

All of the patients who come to the emergency department of "Tehran 7tir Hospital" with trauma to the leg and ankle that need short leg standard splint without any evidence of fracture or dislocation and laceration, will be enroll in this study. Patients under eighteen years

old and those that cannot be following up will be rolled out.

Intervention groups

In case group bracing up will be done by using half size splint (from the toes until middle of the leg) and in the control group it will be done by using a regular splint (from the toes until 4 cm below the knee).

Main outcome variables

Study Indices, including recovery time, duration of pain and swelling, and complications including burn and compartment syndrome, tolerance, pain score in both groups will be compared. These signs and symptoms will be reassessed and recorded during three consecutive weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170105031787N2**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **prospective**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Mohammad-Reza Yasinzadeh

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 5327

Email address

Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2018-02-04, 1396/11/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the immobilization results of lower extremity injuries with two method of short leg standard Splint and half length standard Splint

Public title

Using of short leg splint for immobilization

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Patients, who admitted in the emergency department of "7tir Hospital" in Tehran with a complaint of lower limb trauma and need splinting

Exclusion criteria:

Exclusion criteria: Patients under eighteen years old and those that can not be follow up will be rolled out. Patients who had long bone fracture Patients who had lower limb rupture Patients who had dislocation Patients who had laceration needs to repair

Age

From **18 years** old to **140 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups. In order to randomize, a random block method is used. For this purpose, we formed blocks with 10 person. In each block, 5 individuals will be in short leg standard Splint and 5 will be in half length standard Splint groups. A total of 30 blocks will be considered for sample size. In case group bracing up will be done by using half size splint (from the toes until middle of the leg) and in the control group it will be done by using a regular splint (from the toes until 4 cm below the knee). General information and medical prescription and same advice are implemented

for both groups. Data will analyze by person who is blind to study groups (single blind).

Blinding (investigator's opinion)

Single blinded

Blinding description

Data will analyze by person who is blind to study groups (single blind).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat highway, Tehran,Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.IUMS.FMD.REC.1395.9311307019

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

Lower limb soft tissue injuries

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

recovery time

Timepoint

every week from splinting to removal time

Method of measurement

telephone or in-person interviews with patients

2**Description**

swelling

Timepoint

Before intervention; one week after intervention; two weeks after intervention; three weeks after intervention

Method of measurement

telephone or in-person interviews with patients

3**Description**

pain

Timepoint

every week until 3 weeks from splinting

Method of measurement

telephone or in-person interviews with patients according to pain score

4**Description**

complication such as compartment syndrome, burning of skin or sore

Timepoint

every week from splinting to removal time

Method of measurement

telephone or in-person interviews with patients

5**Description**

tolerance

Timepoint

every week from splinting to removal time

Method of measurement

telephone or in-person interviews with patients

Secondary outcomes

empty

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

Intervention group: Half regular size short splint of lower limb in intervention group

Category

Treatment - Other

2**Description**

Control group: Regular size of short splint of lower limb in control group

Category

Treatment - Other

Recruitment centers**1****Recruitment center**

Name of recruitment center

SHOHADA - E - HAFTE TIR HOSPITAL

Full name of responsible person

Afshin Shokooh Saremi

Street address

Emergency Department, SHOHADA - E - HAFTE TIR HOSPITAL, Shahid rajaee Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1591634312

Phone

+98 21 6641 3523

Email

e_sh.saremi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakooti

Street address

7th Floor, Department of Internal Medicine, Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Afshin Shokooh Saremi

Position

Emergency Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

City

Tehran

Province

Tehran

Postal code

1591634312

Phone

+98 21 6641 3523

Email

e_sh.saremi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad-Reza Yasinzadeh

Position

Assistant Professor of Emergency Medicine

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6652 5327

Fax

Email

yasinzadeh.mr@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Afshin Shokooh Saremi

Position

Emergency Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

Street address

Rasoul-Akram Hospital, Niayesh St., Sattarkahn Ave

City

Tehran

Province

Tehran

Postal code

1591634312

Phone

+98 21 6641 3523

Email

e_sh.saremi@yahoo.com

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