# 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 sience

**Country**

Iran (Islamic Republic of)

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**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
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## 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
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**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

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## Person responsible for scientific inquiries

**Contact**

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Assistant Professor of Emergency Medicine

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Specialist

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## Person responsible for updating data

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**Other areas of specialty/work**
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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