Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between outcome of immobilization of upper limb soft tissue injuries by a regular size splint and half size splint.

Protocol summary

Study aim
Comparison between outcome of immobilization of upper limb soft tissue injuries by a regular size splint and half size 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 hand or wrist that need short arm 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 30 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 hand or wrist that need short arm 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 fingers until middle of the forearm) and in the control group it will be done by using a regular splint (from the fingers until one inch below the elbow). 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 hand or wrist that need short arm 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 fingers until middle of the forearm) and in the control group it will be done by using a regular splint (from the fingers until one inch below the elbow).

Main outcome variables
Study Indices, including recovery time, duration of pain and swelling, and complications including burn and compartment syndrome, 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: **IRCT20170105031787N1**
Registration date: **2017-12-31, 1396/10/10**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-31, 1396/10/10**
Update count: **0**

Registration date
2017-12-31, 1396/10/10

Registrant information

Name
Mohammad-Reza Yasinzadeh

Name of organization / entity
Iran university of medical sience

Country
Iran (Islamic Republic of)

Phone
+98 21 6652 5327

Email address
yasinzadeh.mr@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Iran University of Medical Sciences, Deputy of research

Expected recruitment start date
2017-03-01, 1395/12/11
Expected recruitment end date
2018-03-01, 1396/12/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between outcome of immobilization of upper limb soft tissue injuries by a regular size splint and half size splint.

Public title
Using of short arm 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 upper 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 fracture Patients who had dislocation Patients who had laceration needs to repair
Age
From **18 years** old to **139 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 full-size splint and 5 will be in shorter size 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 fingers until middle of the forearm) and in the control group it will be done by using a regular splint (from the fingers until one inch below the elbow). 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
2015-12-14, 1394/09/23
Ethics committee reference number
IR.IUMS.REC.1394.9311307006

Health conditions studied

1

Description of health condition studied
Upper limb soft tissue injuries
ICD-10 code
S60.1; S60
ICD-10 code description
Contusion of finger(s) with damage to nail; Contusion of other parts of wrist and hand; Multiple superficial injuries of wrist and hand; Other superficial injuries of wrist and hand; Superficial injury of wrist and hand, unspecified; Sprain and strain of

Primary outcomes

1

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 patient

2

Description
recovery time
Timepoint
every week from splinting to removal time
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

Secondary outcomes

empty

Intervention groups

1

Description
Half regular size short splint of upper limb in intervention group
Category
Treatment - Other

2

Description
Regular size of short splint of upper 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
Shahrzad Behjat
Street address
Emergency Department, SHOHADA - E - HAFTE TIR HOSPITAL, Shahid rajaee Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۸۸۶۷۱۸۱۳۶
Phone
+98 21 5522 8585
Email
shahrzad_20us@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
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
Ṣhahrzad Behjat
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
1445613131
Phone
+98 21 6652 5327
Fax
Email
shahrzad_20us@yahoo.com
Web page address

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
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shahrzad Behjat
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
1449614535
Phone
+98 21 6652 5327
Fax
Email
shahrzad_20us@yahoo.com
Web page address

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