Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of oral Aspirin in reducing complex regional pain syndrome (CRPS) in distal radius fractures treated with closed reduction and percutaneous pinning

Protocol summary

Study aim

Evaluation of the effectiveness of oral aspirin in reducing complex regional pain syndrome (CRPS) in distal radius fractures treated with closed reduction and percutaneous pinning

Design

control group was the same as the intervention group. study was double-blinded and randomized. sample size for each group was 40 patients.

Settings and conduct

Location: from August 2016 to September 2017, in the department of Orthopedics Surgery, Hazrat-e Rasool Hospital Study protocol: The protocol was initiated in the emergency department after signature of the informed consent form. The patients were randomly allocated a box containing aspirin or placebo (randomization was performed according to a table of random numbers by the pharmacist), beginning from the emergency department. All boxes and capsules had been made by a pharmacist in the same appearance and taste. Patients were assessed clinically and radiographically at two weeks, four weeks (the cast was shorted), six weeks (pins and cast were removed) and twelve weeks by a physician who was unaware of the treatment allocation. CRPS was clinically assessed with the use of the “Budapest criteria”,

Participants/Inclusion and exclusion criteria

patients 18 years old or over with isolated, extra-articular and low energy distal radius fractures which should be treated with percutaneous pinning

Intervention groups

intervention: perscription of oral aspirin or placebo to intervention group and control group for evaluation of the effectiveness of oral aspirin in reducing complex regional pain syndrome (CRPS) in distal radius fractures intervention group: patients with the mentioned inclusion criteria who receive oral aspirin control group: patients with the mentioned inclusion criteria who receive placebo

Main outcome variables

Complex Regional Pain Syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038391N1**
Registration date: **2018-03-03, 1396/12/12**
Registration timing: **retrospective**

Last update: **2018-03-03, 1396/12/12**
Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Nima Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2264

Email address

hosseinzade.nima@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2017-10-22, 1396/07/30

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of oral Aspirin in reducing complex regional pain syndrome (CRPS) in distal radius fractures treated with closed reduction and percutaneous pinning

Public title

Evaluation of the effectiveness of oral Aspirin in reducing complex regional pain syndrome (CRPS)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

closed, unilateral, extra-articular distal radius fracture eighteen years and over

Exclusion criteria:

history of taking medications that were involved in the treatment of CRPS (such as antidepressants, anticonvulsants, corticosteroids and vitamin C) previous wrist or hand fracture on the same side neurovascular injury fractures with high energy mechanism or multiple trauma-injured patients, multiple fractures at different places contraindication to take aspirin and acetaminophen open fractures articular displacement requiring open reduction

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Actual sample size reached: **91**

Randomization (investigator's opinion)

Randomized

Randomization description

individual randomization with closed envelope

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients were randomly allocated a box containing aspirin or placebo (randomization was performed according to a table of random numbers by the pharmacist). All boxes and capsules had been made by a pharmacist in the same appearance and taste. The study was double-blind. All participants, nurses, physiotherapists, physicians and researchers were unaware of the treatment allocation and the pharmacist was the only individual with the access to the code until the end of the analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Iran University of Medical Sciences

Street address

Hazrat-e Rasool Hospital, Niyayesh Street, Sattarkhan Street

City

Tehran

Province

Tehran

Postal code

Approval date

2017-06-19, 1396/03/29

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311242007

Health conditions studied

1

Description of health condition studied

Complex regional pain syndrome

ICD-10 code

G90.5

ICD-10 code description

Complex regional pain syndrome I (CRPS I)

2

Description of health condition studied

distal radius fracture

ICD-10 code

S62

ICD-10 code description

Fracture at wrist and hand level

Primary outcomes

1

Description

Complex regional pain syndrome

Timepoint

2, 4, 6 and 12 week post operation

Method of measurement

Budapest's criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Aspirin 500mg po daily for 7days
Category
Prevention

2

Description
Control group: placebo capsule daily for 7 daye
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat-e Rasool Hospital
Full name of responsible person
Nima Hosseinzadeh
Street address
Hazrat-e Rasool Hospital, Niyayesh Street, Sattarkhan Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Nima Hosseinzadeh
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Position

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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

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

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

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

Title and more details about the data/document

Information about fractures,medical treatment and the incidence of CRPS

When the data will become available and for how long

After publishing the results in journals

To whom data/document is available

Physicians, physiotherapists

Under which criteria data/document could be used

Only for scientific purposes

From where data/document is obtainable

Email

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

Email

Comments