

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparing the effect of Intravenous Ketorolac and Intravenous Ibuprofen on controlling pain of Colles' fractures in 18 - 45 Y/O patients

Protocol summary

Study aim

The research is a Triple blind RCT held in Besat Hospital that is related to Hamedan University of Medical Sciences. Patients with Colles' fracture coming to Besat Hospital (after being checked for inclusion and exclusion criteria), are divided randomly into two groups. In first one, they receive 400 milligram Ibuprofen and in second one, they receive 30 milligram Ketorolac: both infused over 30 minutes. Pain intensity is recorded with Numerical Rating Scale at 10 minutes before and every 30 minutes (up to 2 times) after intervention.

Design

in this research, 150 patients with Colles' fracture coming to Hamedan Besat Hospital (after being checked for inclusion and exclusion criteria), are included. Participants are divided in 2 groups according to randomized table.

Settings and conduct

this research is held in Emergency Department of Hamedan Besat hospital on visitors with Colles' fracture.

Participants/Inclusion and exclusion criteria

Patients with Colles' fracture and aging between 18 to 45 are included except they have one exclusion criteria.

Intervention groups

75 patients in group 1 receive infused 400 milligram Ibuprofen and 75 patients in group 2 receive infused 30 milligram Ketorolac (both over 30 minutes) and pain score and side effects will be compared between them.

Main outcome variables

Pain, Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160727029109N2**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **retrospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

samiramis pourmotabed

Name of organization / entity

UMSHA

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 2713

Email address

s.pourmotabed@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

empty

Scientific title

Comparing the effect of Intravenous Ketorolac and Intravenous Ibuprofen on controlling pain of Colles' fractures in 18 - 45 Y/O patients

Public title

The pain management efficacy of IV Ibuprofen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age 18-45 y Colles' Fracture

Exclusion criteria:
History of drug abuse Head trauma Increases ICP signs
Altered mental status History of Asthma History of
cardiac problems (CHF - Ischemia) Hemodynamic
instability CVA Allergy to NSAIDs Pregnancy

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Actual sample size reached: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients, get divided randomly into two groups
according to random 5 blocks.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients, medical observer and medical recorders are
unaware of the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamedan University of Medical
sciences

Street address
Rsalat BLV, Besat Hoospital

City
Hamedan

Province
Hamadan

Postal code
6515993466

Approval date
2016-06-25, 1395/04/05

Ethics committee reference number

IR.UMSHA.REC.1395.181

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

2

Description of health condition studied

colles fracture

ICD-10 code

S52.53

ICD-10 code description

Colles' fracture

Primary outcomes

1

Description

Pain management and pain scaling according to
Numerical Rating scale

Timepoint

10 minutes before drug administration and every 30
minutes for 2 times after it

Method of measurement

Numerical Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: ibuprofen infusion receivers

Category

Treatment - Drugs

2

Description

Intervention group: Ketorolac infusion receivers

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Ahmad Hadadian

Street address

Resalat BLVD

City

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Province

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Postal code

6515993466

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Email

samiramispm@yahoo.com

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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

Hamedan University of Medical Sciences

Full name of responsible person

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Mahdieh Street

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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

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

Samiramis Pourmotabed

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Samiramis Pourmotabed

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Samiramis Pourmotabed

Position

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Emergency Medicine

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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