Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of intravenous morphine with morphine plus Pregabalin in trauma patients with extremities' fracture and severe pain

Protocol summary

Summary

Objectives: Pain management is one of the major tasks of any emergency department. Finding a way to better control of pain can result in decreasing staff workload and increasing patient's satisfaction. Design:This is a double blind randomized placebo controlled clinical trial. Setting: This study will be conducted in 3 university hospital emergency departments with 120000 overall annual census. Participant: In this study trauma patients with extremity fracture and verbal numerical pain score (VNRS) more than six between 15 and 60 years old who need admission will be approached. Those with history of addiction, distracting injury and any contraindication to morphine or pregabalin will be excluded. Intervention: They will divided into two group. First group will receive morphine 5 mg with placebo and second group will receive morphine 5 mg and pregabalin 300 mg. Main outcome measures: VNRS and side effects will record in 0-10-30-60 minutes and after that every hour to 6 hours. After 30 minutes if VNRS is above 4, patient will receive rescue dose of morphine 5mg. Total 24 hour morphine doses will be recorded. At the end we will compare VNRS, need to rescue analgesic, side effects and total 24 hour morphine use in these groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412198104N10**
Registration date: **2015-01-25, 1393/11/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-01-25, 1393/11/05

Registrant information

Name
Mohammad Amin Zare
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous morphine with morphine plus Pregabalin in trauma patients with extremities' fracture and severe pain

Public title

Pregabalin in trauma pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Trauma patients with extremity fracture; Verbal Numeric pain score more than 6; Age between 15 or 60 Exclusion Criteria Addiction; Any contraindication for morphine or Pregabalin; Any other

distracting injury; Inability to cooperate

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences' Ethics comittee

Street address
Hemmat Highway, Cross with Sheikh Fazlollah Highway

City
Tehran

Postal code

Approval date
2014-11-12, 1393/08/21

Ethics committee reference number
93/d/105/3390

Health conditions studied

1

Description of health condition studied
Pain in extrimity fracture

ICD-10 code
XIX

ICD-10 code description
Injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description
Severity of pain

Timepoint
0-10 minutes-30 minutes- 1 hour- 6 hours- 12 hours- 18 hours and 24 hours after intervention.

Method of measurement
Using Verbal Numerical Rating Scale (VNRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group receive morphine 5mg and pregabalin 300mg

Category
Treatment - Drugs

2

Description
Control group will receive morphine 5 mg and placebo.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasoul Akram hospital

Full name of responsible person
Mohammad Amin Zare

Street address
Niyayesh St, Sattarkhan Ave

City
Tehran

2

Recruitment center

Name of recruitment center
7th Tir Martyrs Hospital

Full name of responsible person
Mohammad Amin Zare

Street address
Shahid Radjayi Blvd.

City
Tehran

3

Recruitment center

Name of recruitment center
Firouzgar hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Vali Asr Sq. Beh Afarid Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellorfor Research; Iran University of Medical Sciences

Full name of responsible person

Mohammad Amin Zare

Street address

Sattarkhan Ave, Niyayesh St

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellorfor Research; Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assisstant Professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty