

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison between intravenous morphine versus fentanyl efficacy in acute pain relief in drug abuser patients with pain due to acute limb traumatic injury

Protocol summary

Summary

Objective Comparison between intravenous morphine versus fentanyl efficacy in acute pain relief in drug abuser patients with pain due to acute limb traumatic injury Inclusion criteria All patients with traumatic limb pain who are above 18 and have history of opioid addiction enrolled in the study. Exclusion criteria Patients with decreased level of consciousness and history of opioid drug consumption after traumatic injury excluded from the study study population All traumatic limb patients who come to the emergency department of Sina and Shariati Hospital during the study period Sample size Calculated sample size is 320 patients in both group of the study, 160 cases and 160 control patients Interventions and primary outcome This randomized double blind study will conduct in emergency departments of Shariati and Sina Hospitals of Tehran. After signing of informed consent form and explaining the nature of study should determine their pain level score according to VAS. Then patients randomly assigned to each group of study. Group A receive intravenous morphine sulfate 0.1 mg/kg (morphine 10 mg/cc, Daru Pakhsh, Tehran, Iran) and group b receive fentanyl hydro-chloride 1 µg/kg (fentanyl, 500µg/10cc, Abureyhan, Tehran, Iran). Vas score should checked before drug administration and 5, 15, 30, and 60 min after drug administration in both groups. In both group of the study if pain level reduced less than 13 mm after drug administration (morphine or fentanyl) in 5 min after drug administration the rescue dose should be considered.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601308872N10**

Registration date: **2016-02-13, 1394/11/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-13, 1394/11/24

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2719

Email address

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Recruitment status

Recruitment complete

Funding source

deputy of research of Tehran University of Medical Sciences

Expected recruitment start date

2016-02-22, 1394/12/03

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between intravenous morphine versus fentanyl efficacy in acute pain relief in drug abuser

patients with pain due to acute limb traumatic injury

Public title

Effectiveness of intravenous fentanyl in opioid user patients with limb trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age above 18; limb injury; Glasgow coma scale above 14; pain intensity above 5 cm according to visual analogue scale(VAS); past history of opioid usage and history of usage in last week; hemodynamic stability. Exclusion criteria: decrease level of consciousness during drug injection; history of chronic illness(asthma, congenital or acquired heart disease, chronic liver disease, biliary disease, chronic kidney and lung disease); allergy to fentanyl and morphine; lack of cooperation in study process; opioid consumption after acute limb traumatic injury

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **320**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Qods street, keshavarz Blvd

City

Tehran

Postal code

Approval date

2015-09-16, 1394/06/25

Ethics committee reference number

ir.tums.rec.1394.781

Health conditions studied

1

Description of health condition studied

Injury, poisoning and certain other consequences of external causes

ICD-10 code

T10,T11,T1

ICD-10 code description

Fracture of upper limb, level unspecified, Other injuries of upper limb, level unspecified, Fracture of lower limb, level unspecified, Other injuries of lower limb, level unspecified

Primary outcomes

1

Description

pain level of patients

Timepoint

0,5,15,30,60

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

drug complications

Timepoint

After drug prescription

Method of measurement

ABSEVATION AND PATIENT COMPLAIN

2

Description

Patient satisfaction

Timepoint

After pain control

Method of measurement

beck questionnaire

Intervention groups

1

Description

Intervention group (B) receive 1 micro/kg intravenous fentanyl

Category

Treatment - Drugs

2

Description

Group A receive intravenous morphine sulfate 0.1 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Hojat Sheikhmotahar Vahedi

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Hojat Sheikhmotahar Vahedi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh Basti

Street address

Building No 1, North entrance door of Tehran University, Poursina sreet, Qods street, Enghelab street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hojat Sheikh Motahar Vahedi

Position

Assistant professor/ Emergency Medicine specialist

Other areas of specialty/work

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor/ Emergency Medicine specialist

Other areas of specialty/work

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Fax

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Web page address

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