Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of intravenous paracetamol and intravenous morphine sulfate for management of patients with acute limb trauma

Protocol summary

Study aim
The evaluation and comparison of intravenous paracetamol and intravenous morphine sulfate for management of patients with acute limb trauma

Design
In this double blinded, randomized and controlled clinical trial, 180 patients with acute limb trauma are participated and are divided randomly with using random allocation software into two parallel groups as intervention and control group. The intervention group is under treatment with a single dose of paracetamol Intravenously (1 gr paracetamol in 100 ml normal saline solution) and control group is under treatment with a single dose of morphine sulfate Intravenously (0.1 mg/kg in 100 ml normal saline solution).

Settings and conduct
The sampling is done in the emergency department of specialized Baghiyatollah Hospital, Tehran. After patients enrollment according to inclusion and exclusion criteria, patients are divided randomly with using random allocation software into two parallel groups as intervention and control group. The intervention group is under treatment with a single dose of paracetamol Intravenously (1 gr paracetamol in 100 ml normal saline solution) and control group is under treatment with a single dose of morphine sulfate Intravenously (0.1 mg/kg in 100 ml normal saline solution). The patients, doctors, nurses, data collectors, data analyser, are blinded by schedule executive.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the patients with acute limb trauma, ages between 18 to 70 years, weight> 50 kg, systolic blood pressure> 90 mmHg and Visual Analogue Scale >3. Exclusion criteria: patients with severe adverse effect to morphine and paracetamol and discontinuation study

Intervention groups
Intervention group: under treatment with a single dose of paracetamol Intravenously (1 gr paracetamol in 100 ml normal saline solution). Control group: under treatment with a single dose of morphine sulfate Intravenously (0.1 mg/kg in 100 ml normal saline solution).

Main outcome variables
pulse rate, respiratory rate, systolic and diastolic blood pressure , o2 Saturation, visual analogue scale in the baseline and after 30 and 60 minutes of intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130311012782N23**
Registration date: **2018-04-27, 1397/02/07**
Registration timing: **retrospective**

Last update: **2018-04-27, 1397/02/07**
Update count: **0**

Registration date
2018-04-27, 1397/02/07

Registrant information

Name
Ali Mehrabi kushki

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3629 1510

Email address
mehrabi@mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-01-01, 1392/10/11

Expected recruitment end date
2016-12-30, 1395/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of intravenous paracetamol and intravenous morphine sulfate for management of patients with acute limb trauma

Public title
Comparative study of two pain relief paracetamol and morphine in patients with acute limb trauma
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
the patients with acute limb trauma ages between 18 to 70 years weight> 50 kg systolic blood pressure>90 mmHg
Exclusion criteria:
having severe adverse effect in during study don't follow up until end of study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **180**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization: block Unit of randomization: individual Tools used in randomization: Random allocation software Description: Patients are divided randomly into two intervention and control groups by Random Allocation software.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is double blinded which participants, care providers (medicines and nurses), data collectors and outcome assessors are blinded with schedule executive with equal conditions.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baghiatallah University of Medical Sciences
Street address
Baghiatallah University of Medical Sciences, sheykh Bahaie street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
7346181746
Approval date
2015-03-21, 1394/01/01
Ethics committee reference number
IR.Bmsu.rec.1394.25

Health conditions studied

1

Description of health condition studied
acute limb trauma
ICD-10 code
T05.6
ICD-10 code description
Traumatic amputation of upper and lower limbs, any combination [any level]

Primary outcomes

1

Description
Pain severity
Timepoint
before intervention and 30 and 60 minutes after intervention
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: under administration a single dose of paracetamol Intravenous (1 gr paracetamol in 100 ml normal saline solution)

Category
Treatment - Drugs

2

Description
Control group: under administration a single dose of morphine sulfate (0.1 mg/kg in 100 ml normal saline solution)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghiyatollah Hospital
Full name of responsible person
Seyed Nader Naghibi
Street address
Molasadra St
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0435
Email
naghibinader@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Nader Naghibi
Street address
Sheykh-Bahay St
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0436
Email
naghibinader@gmail.com
Web page address
http://www.bmsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Nader Naghibi
Position
Non-faculty specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Sheykh-Bahay St
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0435
Email
naghibinader@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Nader Naghibi
Position
Non-faculty specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Sheykh-Bahay St
City
Tehran
Province
Tehran
Postal code
1435915371

Phone
+98 21 8805 0435
Email
naghibinader@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Seyed Nader Naghibi
Position
Non-faculty specialist
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
Street address
Sheykh-Bahay St
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8805 0435
Email
naghibinader@gmail.com

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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only the results of the whole data are made available to the public
When the data will become available and for how long
starting 3 months after publication
To whom data/document is available
Information is provided to the trauma research center of the Baqiyatallah University of Medical Sciences
Under which criteria data/document could be used
The use of data is merely intended to introduce the study and examine how the parameters are measured
From where data/document is obtainable
Dr. Seyed Nader Naghibi (Project Designer) Address: Baghia Allah Hospital, Mulla Sadra St., Tehran, Iran Phone: 00982188050435 Email: naghibinader@gmail.com Mobile: 00989122990196
What processes are involved for a request to access data/document
1. No use these data in another study 2. Member of the Faculty of Medicine of Baghiyatallah University of Medical Sciences 3. No data access to someone else
Comments