Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Effect of IV Acetaminophen on postoperative pain in patients with Hip fracture

Protocol summary

Study aim
Determine the effect of preoperative intravenous acetaminophen administration on pain after surgery in patients with hip fracture

Design
Clinical trial with control group, Community based and pragmatic, with parallel group, double blind, Randomized with random number table Sample size 66 Trial phase 3

Settings and conduct
This study will be performed in Sabzevar Shahid Beheshti Hospital. The participants were randomly divided into two groups of control and intervention. In the intervention group, intravenous acetaminophen and in the control group will be used normal saline as a placebo, then the pain level of the patients will be evaluate by visual analogue scale and the timing of the application of the first dose of the analgesic and the amount of the analgesic after the operation will be recorded.

Participants/Inclusion and exclusion criteria
Entrance condition: All patient with hip fracture that have age over 15 years; Patient that have not concurrent any fracture; Patients that don't take any analgesic in 6 hour before surgery; Patients that don't have any concurrent surgery; Patients that have not aclocohol or drug abuse; Only patients that take general anesthesia; Patients that be in class 1 and 2 of American Anesthesiology Association Condition of failure to enter: Patients with hepatic failure; Patients with renal failure; Patient with history of drug allergy to IV Acetaminophen

Intervention groups
In intervention group patients receive15 mg/kg of intravenous acetaminophen half an hour before surgery. In control group patients receive 10 cc of normal saline half an hour before surgery.

Main outcome variables
postoperative pain; postoperative analgesic intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180225038861N1**
Registration date: **2018-05-09, 1397/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-09, 1397/02/19**
Update count: **0**

Registration date
2018-05-09, 1397/02/19

Registrant information

Name
Mostafa Jafarpour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 4466 4378

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mostafa_jafarpoor72@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-09, 1396/12/18

Expected recruitment end date
2018-06-19, 1397/03/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of IV Acetaminophen on postoperative pain in patients with Hip fracture

Public title
Effect of iv Acetaminophen on pain in hip fracture
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patient with hip fracture that have age over 15 years Patient that have not concurrent any fracture Patients that don't take any analgesic in 6 hour before surgery Patients that don't have any concurrent surgery Patients that have not aclocohol or drug abuse Only patients that take general anesthesia Patients that be in class 1 and 2 of American Anesthesiology Association
Exclusion criteria:
Patients with hepatic failure Patients with renal failure Patient with history of drug allergy to IV Acetaminophen
Age
From **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study , with the help of random number table patients will be placed in the two of study group.
Blinding (investigator's opinion)
Double blinded
Blinding description
By the nurse of the operating room half an hour before surgery, intravenous acetaminophen will be given to group A and normal saline (placebo) by syringes similar to those of group A will be given to group B patients and patients will not be aware of the contents of the syringe. The evaluator The outcome will also evaluate the outcome without knowing the prescription drug for each group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences
Street address
Ethics committee of Sabzevar University of Medical Sciences, Shohadaye Hastei Blvd., Sabzevar City
City
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Province
Razavi Khorasan
Postal code
9617913114
Approval date
2018-02-18, 1396/11/29
Ethics committee reference number
IR.MEDSAB.REC.1396.139

Health conditions studied

1

Description of health condition studied
Hip fracture
ICD-10 code
S72
ICD-10 code description
Fracture of femur

Primary outcomes

1

Description
The clinical situation of pain
Timepoint
Half an hour after surgery, 4 hours after surgery, 12 hours after surgery and 24 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Iv Acetaminophen is a analgesic drug that in intervention group will be use one time ,half one hour before surgery and with dose 15 mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Shahid beheshti hospital in Sabzevar city
Full name of responsible person
Mostafa Jafarpour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr.Fereshte ghorat
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Research and technology Unit, Sabzevar University of medical sciense, Shodaye Hastei Blvd., Sabzevar
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Mostafa Jafarpour
Position
Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available