

# 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 alcohol 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 receive 15 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4466 4378

##### Email address

mostafa\_jafarpour72@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 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Name of ethics committee</b><br>Ethics committee of Sabzevar University of Medical Sciences                                                                                      |                                                                                                    |
| <b>Public title</b>                                                            | Effect of iv Acetaminophen on pain in hip fracture                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Street address</b>                                                                                                                                                               | Ethics committee of Sabzevar University of Medical Sciences, Shohadaye Hastei Blvd., Sabzevar City |
| <b>Purpose</b>                                                                 | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>City</b>                                                                                                                                                                         | Sabzevar                                                                                           |
| <b>Inclusion/Exclusion criteria</b>                                            | <b>Inclusion criteria:</b><br>All patient with hip fracture that have age over 15 years<br>Patient that have not concurrent any fracture<br>Patients that don't take any analgesic in 6 hour before surgery<br>Patients that don't have any concurrent surgery<br>Patients that have not alcohol or drug abuse<br>Only patients that take general anesthesia<br>Patients that be in class 1 and 2 of American Anesthesiology Association<br><b>Exclusion criteria:</b><br>Patients with hepatic failure<br>Patients with renal failure<br>Patient with history of drug allergy to IV Acetaminophen | <b>Province</b>                                                                                                                                                                     | Razavi Khorasan                                                                                    |
|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Postal code</b>                                                                                                                                                                  | 9617913114                                                                                         |
|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Approval date</b>                                                                                                                                                                | 2018-02-18, 1396/11/29                                                                             |
|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Ethics committee reference number</b>                                                                                                                                            | IR.MEDSAB.REC.1396.139                                                                             |
| <b>Age</b>                                                                     | From <b>15 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Health conditions studied</b>                                                                                                                                                    |                                                                                                    |
| <b>Gender</b>                                                                  | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>1</b>                                                                                                                                                                            |                                                                                                    |
| <b>Phase</b>                                                                   | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Description of health condition studied</b>                                                                                                                                      |                                                                                                    |
| <b>Groups that have been masked</b>                                            | <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>ICD-10 code</b><br>S72                                                                                                                                                           |                                                                                                    |
|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>ICD-10 code description</b><br>Fracture of femur                                                                                                                                 |                                                                                                    |
| <b>Sample size</b>                                                             | Target sample size: <b>66</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>Primary outcomes</b>                                                                                                                                                             |                                                                                                    |
| <b>Randomization (investigator's opinion)</b>                                  | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>1</b>                                                                                                                                                                            |                                                                                                    |
| <b>Randomization description</b>                                               | In this study , with the help of random number table patients will be placed in the two of study group.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Description</b><br>The clinical situation of pain                                                                                                                                |                                                                                                    |
| <b>Blinding (investigator's opinion)</b>                                       | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Timepoint</b><br>Half an hour after surgery, 4 hours after surgery, 12 hours after surgery and 24 hours after surgery                                                            |                                                                                                    |
| <b>Blinding description</b>                                                    | 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.                                                                                                                                                                                             | <b>Method of measurement</b><br>Visual Analogue Scale                                                                                                                               |                                                                                                    |
| <b>Placebo</b>                                                                 | Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Secondary outcomes</b><br>empty                                                                                                                                                  |                                                                                                    |
| <b>Assignment</b>                                                              | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Intervention groups</b>                                                                                                                                                          |                                                                                                    |
| <b>Other design features</b>                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>1</b>                                                                                                                                                                            |                                                                                                    |
| <b>Secondary Ids</b>                                                           | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Description</b><br>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 |                                                                                                    |
| <b>Ethics committees</b>                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Category</b><br>Treatment - Drugs                                                                                                                                                |                                                                                                    |
| <b>1</b>                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Recruitment centers</b>                                                                                                                                                          |                                                                                                    |
| <b>Ethics committee</b>                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>1</b>                                                                                                                                                                            |                                                                                                    |
|                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Recruitment center</b><br><b>Name of recruitment center</b>                                                                                                                      |                                                                                                    |

Shahid beheshti hospital in Sabzevar city

**Full name of responsible person**

Mostafa Jafarpour

**Street address**

Shahid beheshti hospital, Razi ave., Sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617748189

**Phone**

+98 51 4464 0115

**Email**

jafarpourM90@medsab.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Dr.Fereshte ghorat

**Street address**

Research and technology Unit, Sabzevar University of medical science, Shodaye Hastei Blvd., Sabzevar

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617913114

**Phone**

+98 51 4401 8319

**Email**

VCResearch@medsab.ac.ir

**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**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Ground Floor, The last southern house, Andishe 3 ave, Sabzevar City

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9618614341

**Phone**

+98 51 4466 4378

**Email**

jafarpourM90@medsab.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mostafa Jafarpour

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

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**Postal code**

9618614341

**Phone**

+98 51 4466 4378

**Email**

jafarpourM90@medsab.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Mostafa Jafarpour

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Ground Floor, The last southern house, Andisheh 3  
ave, Sabzevar City

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9618614341

**Phone**

+98 51 4466 4378

**Email**

jafarpoorM90@medsab.ac.ir

**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