Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of anesthesia by sodium thiopental with propofol in reducing the need for opiate after tibiofibular fracture surgery

Protocol summary

Summary
In this study, which is carried out on 173 patients in Sabzevar Hospital, Propofol and Thiopental are compared to postoperative need for opioid analgesics. Propofol is a substitute for thiopental. Patients were randomly divided into two groups of study (87 patients) and control (86 patients). The study was performed(Patients did not know the type of medicine) in the IV phase of the study. Anesthesia induction was carried out in the study group with propofol 2 mg / kg, and the control group was 5 mg / kg thiopental. In both groups, heart rate was measured and recorded before induction, after the induction, minutes 1, 5, and 10 after the tracheal intubation. In the 1-2-3-4 hours after the operation, the pain intensity is assessed by the visual scale of the pain. Surgery that lasts more than an hour, and all people with a history of systemic illness and drug addiction are excluded from the study.

General information

Acronym
Patients were randomly divided into two groups (87 patients) and control (86 patients).

IRCT registration information
IRCT registration number: **IRCT2017110733202N6**
Registration date: **2017-11-12, 1396/08/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2017-11-12, 1396/08/21

Registrant information

Name
Atefeh Asadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4422 9180

Email address
a.asadi.mm.1384@gmail.com

Recruitment status
Recruitment complete

Funding source
Investigator

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of anesthesia by sodium thiopental with propofol in reducing the need for opiate after tibiofibular fracture surgery

Public title
Comparison of anesthesia by sodium thiopental with propofol in reducing the need for opiate after tibiofibular fracture surgery

Purpose
Treatment

Inclusion/Exclusion criteria
exclusion criteria: In case of anxiety and lack of response to fentanyl; Surgery longer than 2 hours; All people with a history of systemic disease (cardiovascular, respiratory, hypertension, diabetes, etc.); Patients at risk for nausea and vomiting; Patients with drug addiction or drug addiction. Inclusion criteria: Have personal consent; Surgery is elective.

Age
From **15 years** old to **45 years** old
Gender
Male

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **173**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
no
Secondary trial Id
00
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sabzevar University of Medical Sciences
Street address
Pardis University
City
Sabzevar
Postal code
Approval date
2017-03-15, 1395/12/25
Ethics committee reference number
ir.medsab.rec.1395.146

Health conditions studied

1

Description of health condition studied
Reducing the need for opiate after tibiofibular fracture surgery
ICD-10 code
m96.6
ICD-10 code description
Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate Excl.: complication of internal orthopaedic devices, implants or grafts (T84.-)

Primary outcomes

1

Description
Pain intensity
Timepoint
1-2-3-4 hours after surgery
Method of measurement
Visual Scale of Pain

2

Description
Heart rate
Timepoint
1-2-3-4 hours after surgery
Method of measurement
Examination

3

Description
Narcotic
Timepoint
1-2-3-4 hours after surgery
Method of measurement
MG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After placement of patients on the bed, the necessary monitoring is performed and all injections of midazolam (0.05 mg / kg) and morphine (0.1 mg / kg) are given as premedication. 5 / 0mg / kg intravenous lidocaine is given 90 seconds prior to intubation. Anesthesia induction is performed in the intervention group with propofol 2 mg / kg. Then, 0.5 kg / kg of atracurium was given to both groups and after an intra-chest tracheal intubation of 3 minutes. In both groups, the blood pressure in the heart was measured and recorded before induction (post-prandial) as the base, after induction, minutes 1, 5, and 10 after intubation.
Category
Treatment - Drugs

2

Description
Control group: After placement of patients on the bed, the necessary monitoring is performed and all injections

of midazolam (0.05 mg / kg) and morphine (0.1 mg / kg) are given as premedication. 0.5 mg / kg intravenous lidocaine was given 90 seconds before intubation. Anesthesia was induced in the control group with 5 mg / kg sodium thiopental. Then, 0.5 kg / kg of atracurium was given to both groups and after an intra-chest tracheal intubation of 3 minutes. In both groups, the blood pressure in the heart was measured and recorded before induction (post-prandial) as the base, after induction, minutes 1, 5, and 10 after intubation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdad Hospital - Koshk Street

Full name of responsible person

Adeleh Abdolali zadeh

Street address

Koshk Street

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Sabzevar University of Medical Sciences

Full name of responsible person

fereshteh ghorat

Street address

Pardiss university

City

Sabzevar

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Nematshahi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Asadbadi Street

City

Sabzevar

Postal code

Phone

+98 51 4401 1028

Fax

Email

9151737407mn@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical scinse

Full name of responsible person

Mohammad Nematshahi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Asadbadi Street

City

Sabzevar

Postal code

Phone

+98 51 4401 1028

Fax

Email

9151737407mn@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical sciense

Full name of responsible person

Atefeh Asadi

Position

GP

Other areas of specialty/work

Street address

Talghani Street

City

Sabzevar

Postal code

Phone

+98 51 4422 9180

Fax
Email
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