Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison Effect of etomidate and propofol on delirium and dementia in elderly patients after orthopedic surgery at the hospital Ali ibn Abi Talib in Rafsanjan: a randomized, double-blind,

Protocol summary

Study aim

1- Determination of the effect of two anti-epileptic drugs and propofol on the delirium after surgery, by sex, age and time. 2. Determine the mean score of the dementia test (MMSE) based on sex, age and time 3. Determine the mean score of the Neecham test based on sex, age and time 4- Determination of the effect of two drugs and propofol on the patient's pain after anesthesia by gender, age and time.

Design

A concealed, randomized, blinded, drug controlled clinical trial with a parallel group design of 50 patients, enrolled between Jun 2018 and September 2019

Settings and conduct

In this study, elderly people over 60 years of age who suffered a bone fracture in 96 and 97 years and who were referred to Ali ibn Abi Talib Hospital in Rafsanjan and who were required to undergo general anesthesia surgery. Patients were randomly divided into two groups. Before starting anesthesia and during anesthesia, we monitored the vital signs of the patients. The amount of arterial oxygen saturation and blood pressure were measured every 5 minutes. After this stage, the hypnotic drug (Propofol control group - In-group autoimmunity) was given on the basis of patient weight.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 60 years of age, orthopedic candidate Exclusion criteria: Alcoholism, history of mental disorders (MMSE score less than 23), history of stroke in 6 months before surgery, patient dissatisfaction.

Intervention groups

In the control group, Propofol (2 mg per kg body weight) (manufacturer B, Brun melsungen AG Germany) was used to sleep, and in the Intervention group, an autoantibody (0.2 mg per dose) Kg body weight (manufacturer Janssen-Cilag2012) is used for sleeping.

Main outcome variables

pain- Dementia-Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181206041866N1**
Registration date: **2019-01-29, 1397/11/09**
Registration timing: **retrospective**

Last update: **2019-01-29, 1397/11/09**
Update count: **0**

Registration date

2019-01-29, 1397/11/09

Registrant information

Name
Hossein Ghavipaykar
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-13, 1396/10/23

Expected recruitment end date

2018-09-13, 1397/06/22

Actual recruitment start date

2018-01-13, 1396/10/23

Actual recruitment end date

2018-09-23, 1397/07/01

Trial completion date

2018-10-13, 1397/07/21

Scientific title

Comparison Effect of etomidate and propofol on delirium and dementia in elderly patients after orthopedic surgery at the hospital Ali ibn Abi Talib in Rafsanjan: a randomized, double-blind,

Public title

etomidate and propofol on delirium and dementia in elderly patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Senior citizens over the age of 60 who are candidates for orthopedic surgery Class 1 and ASA class 1 disease Candidate for orthopedic surgery

Exclusion criteria:

Alcohol addiction History of mental disorders (MMSE score less than 23) History of myocardial infarction in 6 months before surgery Patient dissatisfaction

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The patient chooses a sealed envelope in random order

Blinding (investigator's opinion)

Double blinded

Blinding description

All staff involved with the patient in the process include nurses and health professionals A person who measures the status of the patient's consequences is also blinded The patient himself does not know about the drug

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR. Rums. REC. 1396.206

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

F45.41

ICD-10 code description

Pain disorder exclusively related to psychological factors

2

Description of health condition studied

Dementia

ICD-10 code

F01.51

ICD-10 code description

Vascular dementia with behavioral disturbance

3

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

pain

Timepoint

one day - 3 day after operation

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description
Dementia
Timepoint
one and 3 day after operation
Method of measurement
The Mini–Mental State Examination

2

Description
Delirium
Timepoint
One and 3 day after operation
Method of measurement
The NEECHAM Confusion Scale

Intervention groups

1

Description
Intervention group: It is an intravaginal anesthetic drug for induction of anesthesia or sedation that can be used for a short therapeutic course, such as insertion of shoulder joint or tracheal intubation. Its metabolism is essentially carried out with steroid hydrolysis to inactive metabolites, which are then excreted in urine and bile. The duration of the effect period is linearly dependent on the dose, which results in anesthesia with about 0.1 mg / kg per 100 seconds.
Category
Treatment - Drugs

2

Description
Control group: Propofol is a drug from the family of alkaline phenols, which was discovered in the 1970s. Propofol is used in general anesthesia for induction of anesthesia and maintenance of anesthesia in the intensive care unit, and an outpatient outpatient treatment is used in adults with a dose of 1.5-5.5mg / kg / 1 intravenously. Also, side effects of the medicine include the treatment of cholestasis and stroke epilepsy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ebn Abitaleb Hospital
Full name of responsible person
Hossein Ghavipeykar
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh
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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
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Hossein Ghavipeykar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work

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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
There is no further 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
There is no further information
When the data will become available and for how long
There is no further information
To whom data/document is available
There is no further information
Under which criteria data/document could be used
There is no further information
From where data/document is obtainable
There is no further information
What processes are involved for a request to access data/document
There is no further information
Comments