Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating the comparative of pain intensity due to intravenous injection of thiopental sodium, propofol, diazepam and etomidate during induction of general anesthesia

Protocol summary

Study aim

Determination of pain intensity due to intravenous injection of sodium thiopental, propofol, diazepam and etomidate during the induction of general anesthesia

Design

.According to the objectives and type of study and based on previous studies in this field and with the formula and taking into account the assumptions: 5% error and 80% power, 43 people in each group were estimated. Considering the probability of a fall, using the formula, the total sample size was 200 people (50 people in each group).

Settings and conduct

200 selected patients (in 1399) will be selected as available samples and will be randomly divided into four intervention groups based on random blocks and in parallel. In each patient, the demographic questionnaire will be filled in first, and then the pain assessment scale, which is a self-reporting scale, will be measured for each patient at the same time as the injection of the drug being studied while inducing anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Having general anesthesia conditions based on pre-anesthesia examinations 2. Age 15 to 50 years 3. The surgery is optional 4 . Having the risk of anesthesia I and II 5. Do not have drug addiction 6. Do not have mental disorders based on pre-anesthesia examinations 7. Do not have of diabetic disease 8. Do not have systemic neurological disease Exclusion criteria: Non-cooperation of research units with researchers

Intervention groups

Intervention 1: Diazepam is taken as a precursor and no medication has been taken before. Intervention 2: Thiopenthal is taken as a precursor and no medication is taken beforehand. Intervention 3:They take propofol as a precursor and do not take any medication beforehand

Intervention 4: Etomidate is taken as a precursor and no medication is taken beforehand

Main outcome variables

Injection pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190822044581N2**
Registration date: **2020-04-29, 1399/02/10**
Registration timing: **prospective**

Last update: **2020-04-29, 1399/02/10**
Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Naeem Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3222 3853

Email address

naiem.abdi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the comparative of pain intensity due to intravenous injection of thiopental sodium, propofol, diazepam and etomidate during induction of general anesthesia

Public title

Investigating the comparative of pain intensity due to intravenous injection of thiopental sodium, propofol, diazepam and etomidate during induction of general anesthesia

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Having general anesthesia based on pre-anesthesia examinations Age 15 to 50 years The surgery is optional 4 - having the risk of anesthesia I and II Do not have drug addiction Do not have mental and psychological disorders based on pre-anesthesia examinations Do not have diabetic disease Do not have systemic neurological disease

Exclusion criteria:

Non-cooperation of research units with researchers

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasuj University of Medical Sciences

Street address

Motahari street

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

1111111111

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.YUMS.REC.1398.167

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Injection pain

Timepoint

Simultaneously with intravenous injection of the drug

Method of measurement

Pain measurement scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Diazepam is given as a pre-medication at a dose of 0.1 mg / kg and with a volume of 5 cc intravenously and no medication is taken beforehand. Simultaneously with the injection, the severity of the pain is measured by a pain measurement scale, which is a self-reporting scale. After the above medicine, other anesthetic drugs are injected and the patient is anesthetized. This drug is produced by Abu Reihan-Iran Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Second Intervention Group: Sodium thiopental drug is administered intravenously at a dose of 3 mg / kg and with a volume of 5 cc as a sleeping drug and no medication is taken beforehand. Simultaneously with the

injection, the severity of the pain is measured by a pain measurement scale, which is a self-reporting scale. After the above medicine, other anesthetic drugs are injected and the patient is anesthetized. This drug is produced by Abu Reihan-Iran Pharmaceutical Company

Category

Treatment - Drugs

3

Description

Third intervention group: Propofol is administered intravenously as a sleeping drug at a dose of 1 mg / kg and with a volume of 5 cc and no medication has been taken before. Simultaneously with the injection, the severity of the pain is measured by a pain measurement scale, which is a self-reporting scale. After the above medicine, other anesthetic drugs are injected and the patient is anesthetized. This drug is produced by Abu Reihan-Iran Pharmaceutical Company

Category

Treatment - Drugs

4

Description

Fourth Intervention Group: etomidate drug is administered intravenously at a dose of 0.3 mg / kg and with a volume of 5 cc as a sleeping drug and no medication is taken beforehand. Simultaneously with the injection, the severity of the pain is measured by a pain measurement scale, which is a self-reporting scale. After the above medicine, other anesthetic drugs are injected and the patient is anesthetized. This drug is produced by Abu Reihan-Iran Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital in Yasuj
Full name of responsible person
Naeem Abdi
Street address
Motahari street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
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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
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Naeem Abdi
Position
Faculty member
Latest degree
Master
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

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