Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect of Hyoscine N-Butylbromide and Lidocaine 2% on the propofol injection pain

Protocol summary

Study aim
Determination of the effect of hyssine n-butyl bromide and lidocaine 2% on the severity of pain caused by propofol injection

Design
Clinical trial with control group, with parallel groups, blind, randomized

Settings and conduct
This is a randomized clinical trial. The study population consisted of 80 patients aged 20-65 years who are candidates for various surgeries at Heshmatie Hospital in Sabzevar. Four- Point pain scale is used to evaluate pain. painless (0), low pain sensation (1), moderate pain (2), severe pain and with or without movement of the limbs and facial muscles (3). Patients are divided into groups A and B based on random allocation by random numbers table.

Participants/Inclusion and exclusion criteria
Entry requirements: The patient is a candidate for general anesthetic and surgery Age 18-65 The patient has the consent and willingness to participate in the research American Society of Anesthesiology Class I, II Having at least a fifth grade of elementary school Ability to communicate with the research team Non-arrival conditions: Sensitive to the drugs studied Addiction Having Nervous-Muscular Diseases Having heart disease and history of seizures Having metabolic and gastrointestinal disorders Severe nervous and psychiatric disorders Need for induction of anesthesia and rapid intubation Kidney disease in the final stage Liver disorders

Intervention groups
Group A: Propofol injection after 30 seconds of 20 mg Hyoscine injection Group B: Propofol injection after 60 seconds of 2% lidocaine injection at 40 mg

Main outcome variables
Intensity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190109042309N2**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

Registrant information

Name
Zohreh Mohamadzadeh Tabrizi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4401 8329

Email address
mohammadzadehz@medsab.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-06-21, 1398/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the effect of Hyoscine N-Butylbromide and Lidocaine 2% on the propofol injection pain

Public title
Comparison of the effect of Hyoscine N-Butylbromide on the propofol injection pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The patient is a candidate for general anesthetic and surgery ages 18and 65 Ability to communicate with the research team Having at least a fifth grade of elementary school American Society of Anesthesiology Class I, II patient has the consent and willingness to participate in the research
Exclusion criteria:
Addiction Sensitive to the drugs studied Pregnancy Having Nervous-Muscular Diseases Having heart disease and history of seizures Having metabolic and gastrointestinal disorders Severe nervous and psychiatric disorders Need for induction of anesthesia and rapid intubation Kidney disease in the final stage Liver disorders
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this randomized controlled double-blind study, the eligible patients were randomly allocated using random numbers table by computer to one of two groups: the study group and the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, participants and the person evaluating the outcome are blind
Placebo
Not 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
Deputy Director of Research and Technology, University of Medical Sciences, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9717913112-971791311
Approval date
2019-01-19, 1397/10/29
Ethics committee reference number
IR.MEDSAB.REC.1397.102

Health conditions studied

1

Description of health condition studied
Pain caused by injection of propofol
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of pain
Timepoint
At the time of induction of anesthesia
Method of measurement
Assessment of Pain Scores of 4-point Verbal Rating Scale (VRS) during Injection of Propofol

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Propofol injection after 30 seconds of 20 mg Hyoscine
Category
Prevention

2

Description
Control group: Propofol injection after 60 seconds of 2% lidocaine injection at 40 mg
Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmatie Hospital in Sabzevar
Full name of responsible person
Zohreh Mohamadzadeh Tabrizi
Street address
Heshmatie Hospital, Ave Asadabadi, Sabzevar Town.
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114- 96179131
Phone
+98 51 4401 1600
Email
mohamadzadehtz1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zohreh Mohamadzadeh Tabrizi
Street address
Sabzevar University of Medical Sciences, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114- 96179131
Phone
+98 51 4401 8329
Email
mohamadzadehtz1@gmail.com

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
Zohreh Mohamadzadeh Tabrizi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Paramedicine, Sabzevar University of Medical Sciences, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913112
Phone
+98 51 4401 8329
Fax
Email
mohammadzadehz@medsab.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Zohreh Mohamadzadeh Tabrizi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Paramedicine, Sabzevar University of Medical Sciences, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8329
Fax
Email
mohammadzadehz@medsab.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Zohreh Mohamadzadeh Tabrizi
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Faculty of Paramedicine, Sabzevar University of Medical Sciences, Sabzevar
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114- 96179131
Phone
+98 51 4401 8329
Fax
Email
mohammadzadehz@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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is 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
The results of the research are published
When the data will become available and for how long
Starting available 6 months after the publication of results
To whom data/document is available
Internal Scientists at Sabzevar University of Medical Sciences
Under which criteria data/document could be used
Just for reading
From where data/document is obtainable
Email address
What processes are involved for a request to access data/document
Email address
Comments