

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 18 and 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	
<u>1</u>	
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	
<u>1</u>	
Description of health condition studied	Pain caused by injection of propofol
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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	
<u>1</u>	
Description	Intervention group: Propofol injection after 30 seconds of 20 mg Hyoscine
Category	Prevention
<u>2</u>	
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

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Province

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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

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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

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

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Person responsible for scientific inquiries

Contact

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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

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