# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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.
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## 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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**