

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jul 2026

### Investigating the effect of injectable and topical Bupivacaine on post operative pain after rhinoplasty

#### Protocol summary

##### Study aim

The aim of this study is to investigate the amount of postoperative pain and analgesic drug consumption in patients with supraorbital and infraorbital nerve block (BSIB) by bupivacaine, after rhinoplasty surgery.

##### Design

A three-blind randomized clinical trial study with one control group and three intervention groups with parallel groups on 200 patients (each group 50 people). The random block method will be used for randomization.

##### Settings and conduct

Khalili Hospital and Bo Ali Sina Hospital affiliated to Shiraz University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Primary rhinoplasty will be performed in all patients with standard technique and oblique lateral-medial osteotomy. Patients whose physical condition was ASA I based on the American Anesthesiology classification (ASA) and between 17 and 50 years of age will be included in the study. Exclusion criteria are: lack of consent to participate in the study, patients with cardiovascular problems, history of sensitivity to bupivacaine, receiving other anesthetics before and during surgery, and cognitive disorders and inability to communicate and express the level of pain.

##### Intervention groups

Patients who will undergo primary rhinoplasty.

##### Main outcome variables

The amount of nasal pain, the use of analgesics, the amount of nausea-vomiting and postoperative complications

#### General information

##### Reason for update

The actual recruitment start and end date were added.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20131020015083N5**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2025-04-24, 1404/02/04**

Update count: **1**

##### Registration date

2024-02-07, 1402/11/18

##### Registrant information

###### Name

Amir Hossein Babaei

###### Name of organization / entity

Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 917 739 5073

###### Email address

babaei@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2024-07-22, 1403/05/01

##### Actual recruitment start date

2024-02-22, 1402/12/03

##### Actual recruitment end date

2024-07-15, 1403/04/25

##### Trial completion date

empty

##### Scientific title

Investigating the effect of injectable and topical Bupivacaine on post operative pain after rhinoplasty

##### Public title

Investigating the effect of Bupivacaine on post operative

pain after rhinoplasty

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
ASA I physical status based on the American Classification of Anesthesiology (ASA) Age between 17 and 50 years Performing primary rhinoplasty with standard technique and oblique lateral-medial osteotomy  
**Exclusion criteria:**  
Not agreeing to participate in the study Patients with cardiovascular disease History of sensitivity to bupivacaine Receiving other anesthetics before and during the operation Cognitive disorders and the inability to communicate and express the level of pain

**Age**  
From **17 years** old to **50 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **50**  
Actual sample size reached: **55**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Participants were randomly assigned to injection (number 0 in select case) or topical (number 1 in select case), combined (number 2 in select case), and control (number 3 in select case) groups (1:1:1:1 ratio) using random numbers which were generated through computerized block randomization using SPSS software version 23. To reduce selection bias and confounding factors, randomization was performed by a single appointed researcher who did not participate in data collection.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Participant, Care provider, Investigator, Outcome assessor, Data analyser, and Data and Safety Monitoring Board were unaware of the intervention and allocation of treatments until the statistical analysis was complete.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences - Zand street

##### City

Shiraz

##### Province

Fars

##### Postal code

71345-1583

#### Approval date

2024-01-16, 1402/10/26

#### Ethics committee reference number

IR.SUMS.MED.REC.1402.477

## Health conditions studied

### 1

#### Description of health condition studied

patients underwent rhinoplasty

#### ICD-10 code

Z42

#### ICD-10 code description

Encounter for plastic and reconstructive surgery following medical procedure or healed injury

## Primary outcomes

### 1

#### Description

Degree of nasal pain

#### Timepoint

1 hour after the operation, 6 hours after the operation, 1 day after the operation, 2 days after the operation and 3 days after the operation

#### Method of measurement

Visual analog scale (VAS)

### 2

#### Description

analgesic consumption

#### Timepoint

1 hour after the operation, 6 hours after the operation, 1 day after the operation, 2 days after the operation and 3 days after the operation

#### Method of measurement

Asking the patient directly and recording analgesic consumption

## Secondary outcomes

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div>1</div> <div><b>Description</b></div> <div>Nausea-vomiting</div> <div><b>Timepoint</b></div> <div>1 hour after the operation, 6 hours after the operation, 1 day after the operation, 2 days after the operation and 3 days after the operation</div> <div><b>Method of measurement</b></div> <div>Visual analog scale</div> <div>2</div> <div><b>Description</b></div> <div>Postoperative complications</div> <div><b>Timepoint</b></div> <div>up to 7 days</div> <div><b>Method of measurement</b></div> <div>direct physical examination</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <div>1</div> <div><b>Recruitment center</b></div> <div><b>Name of recruitment center</b></div> <div>Ear, Nose and Throat Clinic, Khalili Hospital</div> <div><b>Full name of responsible person</b></div> <div>Dr Reza Kaboodkhani</div> <div><b>Street address</b></div> <div>khalili street</div> <div><b>City</b></div> <div>Shiraz</div> <div><b>Province</b></div> <div>Fars</div> <div><b>Postal code</b></div> <div>7193636981</div> <div><b>Phone</b></div> <div>+98 71 3629 1470</div> <div><b>Fax</b></div> <div></div> <div><b>Email</b></div> <div>kaboodkhani@yahoo.com</div> <div><b>Web page address</b></div> <div></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <div><b>Intervention groups</b></div> <div>1</div> <div><b>Description</b></div> <div>patients who at the end of the operation (before the patient regains consciousness) will be injected with bupivacaine (Marcaine® 0.5%: Aspen Japan; Tokyo, Japan) with a total volume of 4 ml as a local anesthetic.</div> <div><b>Category</b></div> <div>Prevention</div> <div>2</div> <div><b>Description</b></div> <div>Intervention group:There are patients who will be administered local anesthetic bupivacaine (Marcaine® 0.5%: Aspen Japan; Tokyo, Japan) with a total volume of 4 ml at the beginning of the procedure.</div> <div><b>Category</b></div> <div>Prevention</div> <div>3</div> <div><b>Description</b></div> <div>Intervention group: There are patients who receive local bupivacaine through the mesh (each mesh 1 cc, 2 cc in total) at the beginning of the procedure and bupivacaine injection (0.5 cc in each point, 2 cc in total) at the end of the procedure (a total of 4 cc of bupivacaine).</div> <div><b>Category</b></div> <div>Prevention</div> <div>4</div> <div><b>Description</b></div> <div>Control group: No local anesthesia will be used</div> <div><b>Category</b></div> <div>Other</div> <div><b>Recruitment centers</b></div> | <div><b>Sponsors / Funding sources</b></div> <div>1</div> <div><b>Sponsor</b></div> <div><b>Name of organization / entity</b></div> <div>Shiraz University of Medical Sciences</div> <div><b>Full name of responsible person</b></div> <div>Dr Mohammad Hashem Hashempour</div> <div><b>Street address</b></div> <div>Karim Khan Street</div> <div><b>City</b></div> <div>Shiraz</div> <div><b>Province</b></div> <div>Fars</div> <div><b>Postal code</b></div> <div>7134844119</div> <div><b>Phone</b></div> <div>+98 71 3235 7282</div> <div><b>Fax</b></div> <div>+98 71 3235 7282</div> <div><b>Email</b></div> <div>vcrdep@sums.ac.ir</div> <div><b>Grant name</b></div> <div></div> <div><b>Grant code / Reference number</b></div> <div></div> <div><b>Is the source of funding the same sponsor organization/entity?</b></div> <div>Yes</div> <div><b>Title of funding source</b></div> <div>Shiraz University of Medical Sciences</div> <div><b>Proportion provided by this source</b></div> <div>100</div> <div><b>Public or private sector</b></div> <div>Public</div> <div><b>Domestic or foreign origin</b></div> <div>Domestic</div> <div><b>Category of foreign source of funding</b></div> <div>empty</div> <div><b>Country of origin</b></div> <div></div> <div><b>Type of organization providing the funding</b></div> <div>Academic</div> |

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Reza Kaboodkhani  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Ear, Nose, and Throat  
**Street address**  
khalili street  
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7193636981  
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kaboodkhani@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Reza Kaboodkhani  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr Amirhossein Babaei  
**Position**

Resident

### Latest degree

Medical doctor

### Other areas of specialty/work

Ear, Nose, and Throat

### Street address

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### Province

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### Postal code

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### Phone

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### Email

babaei@sums.ac.ir

### Web page address

<https://www.researchgate.net/profile/Amirhossein-Babaei>

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

all collected deidentified IPD

### When the data will become available and for how long

starting 6 months after publication

### To whom data/document is available

only available for people working in academic institutions.

### Under which criteria data/document could be used

there is no specified criteria

### From where data/document is obtainable

corresponding author (09177395073, babaei@sums.ac.ir)

### What processes are involved for a request to access data/document

the request should be sent by email (containing personal and professional information), describing their study protocol, after approving their identity and proposal, the data will be sent by email.

### Comments