

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

1 Description Nausea-vomiting 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 2 Description Postoperative complications Timepoint up to 7 days Method of measurement direct physical examination	1 Recruitment center Name of recruitment center Ear, Nose and Throat Clinic, Khalili Hospital Full name of responsible person Dr Reza Kaboodkhani Street address khalili street City Shiraz Province Fars Postal code 7193636981 Phone +98 71 3629 1470 Fax Email kaboodkhani@yahoo.com Web page address
Intervention groups 1 Description 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. Category Prevention 2 Description 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. Category Prevention 3 Description 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). Category Prevention 4 Description Control group: No local anesthesia will be used Category Other Recruitment centers	Sponsors / Funding sources 1 Sponsor Name of organization / entity Shiraz University of Medical Sciences Full name of responsible person Dr Mohammad Hashem Hashempour Street address Karim Khan Street City Shiraz Province Fars Postal code 7134844119 Phone +98 71 3235 7282 Fax +98 71 3235 7282 Email vcrdep@sums.ac.ir Grant name Grant code / Reference number Is the source of funding the same sponsor organization/entity? Yes Title of funding source Shiraz 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
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
City
Shiraz
Province
Fars
Postal code
7193636981
Phone
+98 71 3629 1470
Email
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
Other areas of specialty/work
Ear, Nose, and Throat
Street address
khalili street
City
Shiraz
Province
Fars
Postal code
7193636981
Phone
+98 71 3629 1470
Email
kaboodkhani@yahoo.com

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
Zand blvd, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7196741475
Phone
+98 917 739 5073
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