

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of local anaesthetic effect of Bupivacaine (Marcaine) VS Bupivacaine and Dexamethasone in Nasal Surgery in Imam hospital of Ahwaz.

Protocol summary

Summary

Goal of study: evaluation the benefits of adding corticosteroids to injection of local anesthesia in reducing the pain and need for analgesics after nasal surgeries. Design of study: a randomized, double-blind, case & control groups, with no placebo, single center. A- Population: All patients requiring nasal surgery - Terms of inclusion: All patients who admitted for different nasal surgeries and went under general anesthesia in Imam Khomeini Hospital in Ahwaz. - Terms of exclusion: Having a history of major cardiovascular diseases, hypertension, cerebrovascular accidents, diabetes, eye problems or a history of hypersensitivity to local anesthetic agents such as lidocaine or their preservative compounds. - Sample: 60 patients B- Interventions: local injections (nerve blocks) in nasal area using Dexamethasone with Marcaine (Bupivacaine) against Marcaine. C- Time of intervention: Before nasal surgery and after induction of general anesthesia. D- Outcomes studied: Reduce the pain or application of oral/injectable analgesics after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104256288N1**
Registration date: **2011-09-04, 1390/06/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-04, 1390/06/13

Registrant information

Name

Mahmood Hekmat shoar

Name of organization / entity

Ahwaz Jundi shapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1333 3477

Email address

hekmat-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahwaz Jundi shapour University of Medical Sciences.

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of local anaesthetic effect of Bupivacaine (Marcaine) VS Bupivacaine and Dexamethasone in Nasal Surgery in Imam hospital of Ahwaz.

Public title

The role of adding topical corticosteroids in anesthesia and analgesia after nasal surgery.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: All patients who admitted for nasal surgery (closed reduction of nasal bone fracture (NBF), septoplasty, rhinoplasty, endoscopic sinus surgery (FESS))

or a combination of them) and went under general anesthesia in Imam Khomeini Hospital in Ahwaz. Exclusion Criteria: 1- Not in the specified age range. 2- Having a history of major cardiovascular diseases, hypertension, cerebrovascular accidents, diabetes and eye problems. 3- Having a history of hypersensitivity to local anesthetic agents such as lidocaine or their preservative compounds. 4- Lack of satisfaction or cancellation to participate in the study. 5- Not undergoing general anesthesia for any reason.

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jundi shapour University of Medical Sciences

Street address

Department of research and technology,Ahwaz Jundi shapour University of Medical Sciences,University center,Golestan highway.Post box:45

City

Ahwaz

Postal code

61357-15794

Approval date

2011-06-18, 1390/03/28

Ethics committee reference number

ETH-169

Health conditions studied

1

Description of health condition studied

local anaesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

2

Description of health condition studied

Closed reduction of nasal bone fracture

ICD-10 code

S02.2

ICD-10 code description

Fracture of nasal bones

3

Description of health condition studied

Septoplasty

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

4

Description of health condition studied

Rhinoplasty

ICD-10 code

M95.0

ICD-10 code description

Acquired deformity of nose

5

Description of health condition studied

FESS(Functional endoscopic sinus surgery)

ICD-10 code

J32,J33

ICD-10 code description

Chronic sinusitis,Nasal polyp

Primary outcomes

1

Description

The amount of postoperative pain

Timepoint

1,2,4,6,12,24 heures after surgery

Method of measurement

Visual Analog Scale(VAS)

2

Description

The need for oral or injectable analgesic drugs

Timepoint

In the first 24 hours after surgery

Method of measurement

Frequency of use of acetaminophen 325mg (oral tablets) or pethidine 20mg(intravenous injection)

Secondary outcomes

empty

Intervention groups

1

Description

In the control group, injectable solution of Marcaine is used for nerve blocking(Incisive nerve (columellar area),bilateral Infraorbital nerves and Supratrochlear nerves) during surgery and immediately after general anesthesia. We used 5-20 cc of 0.5% Marcaine solution (dose=1-1.5 mg/kg,max dose=100 mg per patient).

Category

Other

2

Description

In the intervention group, injectable solution of Marcaine + Dexamethasone is used for nerve blocking(Incisive nerve (columellar area),bilateral Infraorbital nerves and Supratrochlear nerves) during surgery and immediately after general anesthesia. We used 5-20 cc of 0.5% Marcaine solution (dose=1-1.5 mg/kg,max dose=100 mg per patient) and 2-8 mg of Dexamethasone solution in each patient(dose=0.1 mg/kg).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Mahmood Hekmat shoar

Street address

Otorhinolaryngology Department,Imam Khomeini Hospital,Azadegan(24 metri) Avenue

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundi shapour University of Medical Sciences

Full name of responsible person

Doctor Mostafa Fegh'hi,Deputy of research and Technology in Ahwaz University of Medical Sciences

Street address

Department of research and technology,Ahwaz Jundi shapour University of Medical Sciences,University center,Golestan highway.Post box:45

City

Ahwaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahwaz Jundi shapour University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz Jundi shapour University of Medical Sciences

Full name of responsible person

Doctor Mahmood Hekmat shoar

Position

Assistant of Otorhinolaryngology

Other areas of specialty/work

Street address

Ahwaz Jundi shapour University of Medical Sciences,University center,Golestan highway

City

Ahwaz

Postal code

61357-15794

Phone

+98 61 1333 3477

Fax

+98 61 1336 1544

Email

dr.mhekmat@yahoo.com

Web page address

www.ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahwaz Jundi shapour University of Medical Sciences

Full name of responsible person

Doctor Abdol-hosein Ma'soomi

Position

Otorhinolaryngologist,Fellowship of Head and Neck Surgery,Assistant Professor

Other areas of specialty/work

Street address

Ahwaz Jundi shapour University of Medical Sciences,University center,Golestan highway.

City

Ahwaz
Postal code
61357-15794
Phone
+98 61 1333 3477
Fax
+98 61 1336 1544
Email
dr.mhekmata@yahoo.com
Web page address
www.ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahwaz Jundi shapour University of Medical Sciences
Full name of responsible person
Doctor Mahmood Hekmat shoar
Position
Assistant of Otorhinolaryngology
Other areas of specialty/work
Street address
Ahwaz Jundi shapour University of Medical Sciences, University center, Golestan highway.
City
Ahwaz

Postal code
61357-15794
Phone
+98 61 1333 3477
Fax
+98 61 1336 1544
Email
dr.mhekmata@yahoo.com
Web page address
ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty