

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the effect of using Ropivacaine injection after surgery in comparison with routine care on pain and nausea after surgery in patients candidate for mandibular orthognathic surgery.

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of postoperative topical injection of Ropivacaine, on postoperative pain and nausea, in mandibular orthognathic surgery.

Design

The two intervention and control groups each consisted of 10 male patients who were simply randomized and the study was double-blind.

Settings and conduct

Selection of patients who are candidate for mandibular surgery in the surgery department of Mashhad Dental School and then Performing surgery in Ghaem Hospital of Mashhad

Participants/Inclusion and exclusion criteria

Gender of patients: Male Entry conditions: Do not have systemic disease, especially kidney disease No entry conditions: In terms of systematic classification, they are in ASA-I, ASA-II categories.

Intervention groups

In the intervention group, injections of Ropivacaine are performed after surgery. In the control group, Ropivacaine is not injected.

Main outcome variables

A new guide to reducing common pain and nausea after mandibular orthognathic surgery with topical postoperative injection of Ropivacaine. Response to disagreement about the effect of long-acting local anesthetics on postoperative pain and nausea in mandibular orthognathic surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181023041425N2**

Registration date: **2020-10-14, 1399/07/23**

Last update: **2020-10-14, 1399/07/23**

Update count: **0**

Registration date

2020-10-14, 1399/07/23

Registrant information

Name

Majid Hosseini Abrishami

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of using Ropivacaine injection after surgery in comparison with routine care on pain and nausea after surgery in patients candidate for mandibular orthognathic surgery.

Public title

The effect of ropivacaine on pain and nausea after maxillofacial surgery.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Male patients with mandibular defect Examination in the surgical department of Mashhad Dental School and then performing mandibular orthognathic surgery in Ghaem Hospital of Mashhad These patients are ASA-I and ASA-II in terms of systemic classification.
Exclusion criteria:
 Existence of systemic disease, especially kidney disease
 The need to use a drug outside the standard protocol of anesthesia or after surgery depending on the patient's condition

Age
No age limit

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: 20

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using a table of random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
In the intervention group, the patient and his clinical caregivers are unaware of Ropivacaine's injection that is done immediately after surgery.

Placebo
Not used

Assignment
Parallel

Other design features
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Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Science, Daneshgah Ave, Mashhad, Iran

City

Mashhad
Province
 Razavi Khorasan
Postal code
 9138813944

Approval date

2019-10-02, 1398/07/10

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.081

Health conditions studied

1

Description of health condition studied

Mandibular surgery

ICD-10 code

M26.19

ICD-10 code description

Other specified anomalies of jaw-cranial base relationship

Primary outcomes

1

Description

Postoperative pain and nausea

Timepoint

1,3,6,12,18,24 Hours after surgery

Method of measurement

using pain and nausea questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Rupivacaine's injection after surgery

Category

Treatment - Drugs

2

Description

Do not inject Rupivacaine and perform routine care after surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dentistry School

Full name of responsible person

Hoseini Abrishami Majid

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Dentistry School, VakilAbad Bolvard , Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghaem Hospital

Full name of responsible person

Alipour Mohammad

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Ghaem Hospital, Mashhad

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Grant name

Grant code / Reference number

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

No

Title of funding source

Proportion provided by this source

1

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

Mashhad Dentistry School

Full name of responsible person

Hoseini Abrishami Majid

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Maxillofacial Surgery

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Person responsible for scientific inquiries

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Maxillofacial Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad Dentistry School

Full name of responsible person

Meidandar Mahdi Shamsoldin

Position

General dentistry student

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

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When the data will become available and for how long

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To whom data/document is available

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Under which criteria data/document could be used

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From where data/document is obtainable

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

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Comments

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