Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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

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 Rupivacaine. 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**
Registration timing: **registered_while_recruiting**

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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Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghaem Hospital
Full name of responsible person
Alipour Mohammad
Street address
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
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Person responsible for updating data

Contact

Name of organization / entity
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Meidandar Mahdi Shamsoldin

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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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