

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of using Ropivacaine as a long acting anesthesia on systemic factors, amount of using opioid and bleeding during operation and post-operative pain in orthognathic surgery comparing with lidocaine

Protocol summary

Study aim

The purpose of this study is to evaluate effect of using Ropivacaine on systemic factors, use of opioids and bleeding during orthognathic surgery and post operative pain control comparing with use of Lidocaine.

Design

Two arm parallel group randomised trial with double blinding

Settings and conduct

The patients with cl III skeletal deformity up to 10 milimeters will be bedded at maxillofacial surgery service at Ghaem hospital of Mashhad. Patients are divided to two 20 groups. At first group 2cc Ropivacaine 0/5% at BSSO incision site and 4cc at Lefort incision site will be used. At the second group 1/8cc Lidocaine 2% with Epinephrine 1/100000 at BSSO incision site and 3/6cc at Lefort incision site will be used. Then during operation amounts of using opioids, amounts of bleeding with suctioned bloods, systemic factors including heart rate, mean arterial pressure, breathing, SPO₂ with monitoring device will be measured at each group and will compare with each other. Also amounts of pain after operation at each group will be measured at 2, 6, 12, 18, 24 hours after operation via VAS scale and compared with each other. This study is double blinded and blinding is done for patients under study and analysts.

Participants/Inclusion and exclusion criteria

patients with cl III deformity up to 10 milimeters is the condition of entrance to study and presence of systemic disease especially kidney disease is the condition of not entering to study.

Intervention groups

The intervention group at this study consists of patients candidate for orthognathic surgery that Ropivacaine is used as preoperative local anesthesia.

Main outcome variables

Amounts of using opioids during operation; Amounts of

bleeding; Amounts of systemic factors including mean arterial pressure, breathing, heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170718035163N1**

Registration date: **2019-07-20, 1398/04/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-20, 1398/04/29**

Update count: **0**

Registration date

2019-07-20, 1398/04/29

Registrant information

Name

Mozhgan Kazemian

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of using Ropivacaine as a long acting anesthesia on systemic factors, amount of using opioid and bleeding during operation and post-operative pain in orthognathic surgery comparing with lidocaine

Public title

Evaluation of using Ropivacaine in orthognathic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients who have cl III with discrepancy up to 10 mm.

Exclusion criteria:

The patients who have systemic diseases especially kidney disease. The patients who have history of allergy to drugs using in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method of this study is blocked. This method is used to prevent significant imbalances in the number of participants assigned to each group. This randomization guarantees that during periods of randomization, no significant imbalance exists between groups. For this method, the size of each block must first be determined and then write the list of blocks and assign them numbers. The randomization unit is individual. The randomization tool is Statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study blinded groups involves patients and persons who analyses the data. Participants will be unaware of the fact that they receive Ropivacaine or Lidocaine (of course during signing moral Satisfaction form, they will be notified if they receive one of these two drugs.) Data will be grouped into groups A and B for delivery to the statistician. The statistician is unaware of which group of drugs he received.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of mashhad university of medical Sciences

Street address

Qoreyshi building, facing 18th Daneshgah, Daneshgah street, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91735

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.011

Health conditions studied**1****Description of health condition studied**

Cl III jaw deformity

ICD-10 code

K07.1

ICD-10 code description

Anomalies of jaw-cranial base relationship

Primary outcomes**1****Description**

Systemic factors including heart rate, mean arterial pressure, breathing, SpO2

Timepoint

Evaluating systemic factors 15, 30, 45, 60, 75, 90, 105, 120 minutes after starting the surgery.

Method of measurement

Monitoring device

Secondary outcomes**1****Description**

Evaluating the amounts of pain after surgery

Timepoint

Evaluating pain 2, 6, 12, 18, 24 hours after surgery

Method of measurement

VAS scale

2

Description

Amounts of using narcotics during surgery

Timepoint

Measuring narcotic consumption after starting surgery

Method of measurement

Determined by anesthetic team.

Intervention groups

1

Description

Intervention group: includes group that 2cc Ropivacaine 0/5% (naropin) as preoperative anesthesia at BSSO incision and 4cc at lefort incision before beginning orthognathic surgery are used.

Category

Treatment - Surgery

2

Description

Control group: includes group that 1/8cc Lidocaine 2% with epinephrine 1/80000 (Persocaine) as preoperative anesthesia at BSSO incision and 3/6cc at lefort incision before beginning orthognathic surgery are used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Mozhgan Kazemian

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Ahmad abad Blvd, ghaem hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Mohsen Tafaghodi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

70

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 University of Medical Sciences

Full name of responsible person

Mozhgan Kazemian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mozhgan Kazemian

Position

Assistante professor

Latest degree

Specialist