Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of pre-operative administering of oral Montelukast on the pain amount following orthognathic surgery.

Protocol summary

Study aim
Evaluating the amount of pain after administration of a single dose of 10mg montelukast tablet one hour before the bimaxillary orthognathic surgery

Design
A clinical trial with a control group, with parallel groups, triple blinded, randomized, phase 3 on 60 patients. The patient, surgeon, outcome assessor, and statistical analyzer will not be aware of the study groups. Block randomization will be done by the computer software "Random Allocation Software".

Settings and conduct
Setting: Maxillofacial department of Qhaem Hospital, Mashhad. The patients, the surgeon, the outcome assessor, and the data analyzer would not be aware of the administered drugs.

Participants/Inclusion and exclusion criteria
The inclusion criteria include: 1.Patients suffering from skeletal class 3 deformity, requiring advancement of the maxilla with Lefort1 and setback of the mandible with BSSO (Bilateral Sagittal Split Osteotomy) technique. 2.Patients between 18 to 40 years old.3.Patients who are categorized in the 1st and 2nd group of the ASA classification.4.Patients who completed the informed consent. The Exclusion criteria include 1.Patients with a history of using analgesics or psychiatric medication during the previous month.2.Patients with a history of addiction or psychological problems 3.Patients with a history of drug allergy.4.Patients with a history of severe sinusitis.

Intervention groups
Intervention group: A single dose of 10 mg oral montelukast tablet (made by Abidi pharmaceutical company under the brand name Airokast) will be dissolved in 20cc of apple juice and will be administered 1 hour before the surgery. Control group: Administration of 20cc of natural apple juice in which no drug or substance is dissolved as a placebo one hour before the surgery.

Main outcome variables
The amount of pain using the Visual analog scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150613022697N8**
Registration date: **2020-12-02, 1399/09/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-02, 1399/09/12**
Update count: **0**

Registration date
2020-12-02, 1399/09/12

Registrant information

Name
Sahand Samiee rad

Name of organization / entity
mashhad dental school,oral and maxillofacial department

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-21, 1399/07/30

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of pre-operative administering of oral Montelukast on the pain amount following orthognathic surgery.

Public title
Evaluating the effect of Montelukast on pain following orthognathic surgery.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients suffering from skeletal class 3 deformity, requiring advancement of the maxilla and set back of mandible using Lefort 1 and BSSO (Bilateral Sagittal Split Osteotomy) technique respectively. Patients between 18 to 40 years old. Patients who are categorized in the 1st and 2nd group according to the ASA (American Society of Anesthesiology) Patients who completed the informed consent.
Exclusion criteria:
Patients with a history of using analgesics or psychiatric medication during the previous month. Patients with a history of addiction or psychological problems . Patients with a history of drug allergy. Patients with a history of severe sinusitis .
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Since the two groups are supposed to have the same sample size, the restricted randomization method and permuted block randomization will be used in this study. Random block units will usually be used to balance the number of samples assigned to each of the groups studied. The size of blocks will be selected randomly and there is an equal number of each group in each block. Creating a random sequence will be performed by computer software " Random Allocation Software". Random allocation concealment will be done using sequentially numbered, sealed, opaque envelopes by an independent person who does not know the study process.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the patient, surgeon, outcome assessor, and statistical analyzer will not be aware of the study groups. Regarding patients, blinding is so that patients will not know if they will receive a drug or a placebo. Regarding the assessor, the operator who delivers the pain questionnaires to the patient and completing the study checklist is not aware of the group assignment. The statistical analyzer will be blinded and all data will be provided in the form of coding to him. Furthermore, the anesthesiologist was aware of the drug types in order to prevent the peri- and postoperative complications.
Placebo
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 Science
Street address
Ghoreishi building, Daneshghah avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Approval date
2020-09-02, 1399/06/12
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1399.053

Health conditions studied

1

Description of health condition studied
Pain in Jaws
ICD-10 code
K10.9
ICD-10 code description
Disease of jaws, unspecified

Primary outcomes

1

Description
Amount of pain in the specified time period.
Timepoint

1 hour before the surgery and also 1 ,3 ,6 , 12 , 18 ,and 24 hours after the surgery.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One dose of 10 mg oral montelukast tablet (made by Abidi pharmaceutical company under the brand name Airokast) will be dissolved in 20cc of apple juice and will be administered to the patients 1 hour before the surgery.

Category

Rehabilitation

2

Description

Control group: Administration of 20cc of natural apple juice in which no drug or substance is dissolved as placebo one hour before the surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and maxillofacial surgery department of Qaem hospital , Mashhad

Full name of responsible person

Sahand Samieerad

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Mashhad Qaem hospital, Ahmadabad boulvard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

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

Mashhad University of Medical Sciences

Full name of responsible person

Sahand Samieerad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.

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Person responsible for scientific inquiries

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Full name of responsible person
Sahand Samieerad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

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Position
student

Latest degree
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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
All collected data would be shared for all researchers after the participants were unidentified.

When the data will become available and for how long
The access to data will be started 6 months after publication

To whom data/document is available
The data would only be available for people working in academic institutions.

Under which criteria data/document could be used
It is allowed to use the data for meta-analysis and systematic reviews.

From where data/document is obtainable
The data can be obtained via email, from the corresponding researches (Dr Sahand samiee rad). E-mail: samieerads@mums.ac.ir

What processes are involved for a request to access data/document
The new research proposal and the processes details should be e-mailed to corresponding researcher in order to get the access permission

Comments