Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The evaluation of oral Montelukast prescription effect on the amount of nasal congestion of patients following orthognathic surgery.

Protocol summary

Study aim
Evaluating the amount of nasal congestion after administration of a single dose of 10mg Montelukast tablet one hour before the bimaxillary orthognathic surgery and once a day for 1 week postoperatively.

Design
A clinical trial with a control group, with parallel groups, triple blinded, randomized, phase 3 on 66 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
A randomized triple-blinded clinical trial with a control group in the maxillofacial department of Ghaem Hospital, Mashhad. The patients, surgeon, outcome assessor, and 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 groups of the ASA classification. 4. Patients who completed the informed consent. The Exclusion criteria include 1. Patients with a history of sinus diseases, sinus infections, and allergies. 2. Patients with a history of smoking and alcohol.

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 10cc of apple juice and will be administered 1 hour before the surgery and once a day after the surgery for 1 week. Control group: Administration of 10cc of natural apple juice in which no drug or substance is dissolved as a placebo one hour before the surgery and once a day after the surgery for 1 week.

Main outcome variables
Rate of nasal congestion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150613022697N12**
Registration date: **2022-07-05, 1401/04/14**
Registration timing: **prospective**

Last update: **2022-07-05, 1401/04/14**
Update count: **0**

Registration date
2022-07-05, 1401/04/14

Registrant information

Name
Sahand Samiee rad
Name of organization / entity
mashhad dental school,oral and maxillofacial department
Country
Iran (Islamic Republic of)
Phone
+98 51 3883 7289
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-01, 1401/05/10
Expected recruitment end date
2023-11-01, 1402/08/10
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of oral Montelukast prescription effect on the amount of nasal congestion of patients following orthognathic surgery.

Public title
Evaluating the effect of Montelukast on the amount of nasal congestion following orthognathic surgery
Purpose
Treatment
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 sinus diseases, sinus infection, and allergy. Patients with a history of smoking and alcohol. Patients with a history of cleft palate.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **66**
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 take the rhinomanometry test 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
2022-06-28, 1401/04/07
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1401.045

Health conditions studied

1

Description of health condition studied
Rate of nasal congestion
ICD-10 code
J01.0
ICD-10 code description
Acute maxillary sinusitis

Primary outcomes

1

Description
Rate of nasal congestion in the specified time period.
Timepoint
1 week before and 1 week after the surgery
Method of measurement

Rhinomanometry test

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 10cc of apple juice and will be administered to the patients 1 hour before the surgery and once a day after the surgery for 1 week.
Category
Rehabilitation

2

Description
Control group: Administration of 10cc of natural apple juice in which no drug or substance is dissolved as placebo one hour before the surgery and once a day after the surgery for 1 week.
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
Street address
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
Dr. Majid Ghayour mobarhan
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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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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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student

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Dentistry

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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