Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

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

Protocol summary

Study aim
Evaluating the amount of pain after administration of a single dose of 4mg Tizanidine tablet one hour before the bimaxillary orthognathic surgery.

Design
A clinical trial with a control group, with parallel groups, double 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
Inclusion criteria : 1-Patients suffering from skeletal class 3 deformity, requiring advancement of the maxilla and set back of mandible . 2-Patients between 18 to 40 years old.3- Patients who completed the informed consent. 4-Patients who are categorized in the 1st and 2nd group according to the ASA 5- BMI index less than 30kg/m The Exclusion criteria 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 chronic pain 5-Patients with a history of low blood pressure and bradycardia 6-Patients with a history of using ciprofloxacin and Fluoxetine7- Patients who want to leave the trial by any reason

Intervention groups
Intervention group: A single dose of 4 mg oral Tizanidine tablet will be dissolved in 10cc of apple juice and will be administered 1 hour before the surgery. 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.

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

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150613022697N10**
Registration date: **2020-12-05, 1399/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-05, 1399/09/15**
Update count: **0**

Registration date
2020-12-05, 1399/09/15

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
Email address
samieerads@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-20, 1399/08/30
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 Tizanidine on the pain amount following orthognathic surgery.

Public title
Evaluating the effect of Tizanidine 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 completed the informed consent. Patients who are categorized in the 1st and 2nd group according to the ASA (American Society of Anesthesiology) BMI index less than 30kg/m2
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 chronic pain Patients with a history of low blood pressure and bradycardia Patients with a history of using ciprofloxacin and Fluoxetine Patients who want to leave the trial by any reason
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)
Double 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
Ghoreshi building, Daneshghah avenue
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Approval date
2020-11-04, 1399/08/14
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1399.080

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 ,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: Intervention group: One dose of 4 mg oral Tizanidine will be dissolved in 10cc of apple juice and will be prescribed to the patients 1 hour before the surgery.Tizanidine will be prescribed in one dose before surgery and the anti pain features will assessed after operation. Tizanidine is and alpha2 agonist from clonidine derivations which inhibits excitatory neurons
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
Street address
Mashhad Qaem hospital, Ahmadabad boulvard
City
Mashhad
Province
Razavi Khorasan
Postal code
9176999311
Phone
+98 51 3840 0000
Email
samieerads@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Mohsen Tafaghodi
Street address
Ghoreshi building, Daneshghah avenue.
City
Mashhad
Province
Razavi Khorasan
Postal code
91779448959
Phone
+98 51 3841 2081
Email
TafaghodiM@mums.ac.ir
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
Street address
oral and maxillofacial surgery department, Mashhad dental school, Vakil abad street.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959
Phone
+98 51 3882 9501
Fax

+98 51 3882 9500

Email

samieerads@mums.ac.ir

Person responsible for scientific 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

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3882 9501

Fax

+98 51 3882 9500

Email

samieerads@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saleh Dadmehr

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Phone

+98 51 3761 5938

Email

dadmehrs961@mums.ac.ir

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