Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of two methods of medial ramus osteotomy in sagittal split osteotomy ((standard method and parallel osteotomy))for easiness and post operation complication

Protocol summary

Study aim
Comparison of two methods of medial ramus osteotomy in sagittal split osteotomy (standard method and parallel osteotomy) for easiness and post operation complication
Design
This clinical trial contain group of control with sagital split osteotomy surgery and case group with medial parallel osteotomy. In both group we have 18 patients.
Settings and conduct
The surgery has been done by maxilofacial surgery resident under general anesthesia in operating room
Participants/Inclusion and exclusion criteria
Patient with skeletal class 2&3 deformity
Intervention groups
In intervention group use medial paralell osteotomy that less manipulation in nerve location needed vs in control group sagittal split osteotomy that we need exposure of nerve entrance.
Main outcome variables
Soft tissue anesthesia and bone fracture

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230313057709N1**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**
Registration date
2023-06-18, 1402/03/28

Registrant information
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-15, 1402/03/25
Expected recruitment end date
2023-06-16, 1402/03/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of two methods of medial ramus osteotomy in sagittal split osteotomy ((standard method and parallel osteotomy))for easiness and post operation complication

Public title
Comparison of two methods of mandibular osteotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with skeletal class 2&3
Exclusion criteria:
Patients that need genioplasty Patients with mandibular nerve abnormalities

Age
From **16 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **18**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Soffeh blvd.
City
Isfahan
Province
Isfehan
Postal code
8185798646
Approval date
2023-06-06, 1402/03/16
Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.375

Health conditions studied

1

Description of health condition studied
patients with skeletal deformity
ICD-10 code
K07.1
ICD-10 code description
Anomalies of jaw-cranial base relationship

Primary outcomes

1

Description
Chin and lower lip anesthesia after the surgery
Timepoint
Before and after the surgery
Method of measurement
Two point discrimination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: medial paralel osteotomy
Category
Treatment - Surgery

2

Description
Control group: sagital split osteotomy
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Mohamad Hasan Samandari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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Abbas Amiri
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohamad Hasan Samandari
Position
Assistant professor
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable

Title and more details about the data/document

medial parallel osteotomy

When the data will become available and for how long

6monthes after publish

To whom data/document is available

all the people

Under which criteria data/document could be used

orthognathic surgery

From where data/document is obtainable

isfahan university of medical science faculty of dentistry

What processes are involved for a request to access data/document

refer to the library of faculty of dentistry

Comments