

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 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 sagittal 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 maxillofacial 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 parallel 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

Name

Amirreza Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3766 5017

Email address

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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

Isfahan

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

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Abbas Amiri

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Faculty of Dentistry, Soffeh blvd.

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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

Latest degree

Specialist

Other areas of specialty/work

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

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