

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A Comparative study to assess feasibility of computer assisted designed and fabricated surgical guides in sagittal split osteotomy vs. conventional sagittal split osteotomy.

Protocol summary

Study aim

To make a comparative study between computer designed and manufactured surgical guide assisted sagittal split osteotomy of mandibular ramus and conventional sagittal split osteotomy of ramus.

Design

A randomized triple blinded clinical trial study is designed to compare computer designed and fabricated surgical guide assisted sagittal split osteotomy and conventional sagittal split osteotomy. The study will be conducted on patients that will be visited at Oral and Maxillofacial Surgery Department of Sina Hospital, Tehran University of Medical sciences, Tehran, Iran.

Settings and conduct

The entire patients who have sagittal split osteotomy in their treatment plan will be included in this study. The study subjects are recruited depending on their treatment plan from clients visited at Oral and Maxillofacial Surgery Department of Sina Hospital (Tehran/ Iran). In this study the trial participant, surgeon who will assess the inferior alveolar nerve neurosensory disturbance during follow and statistician will be blinded. they will not know which side is treated conventionally or with the assist of surgical guide..

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 35. Patients who have sagittal split osteotomy in their treatment plan.
Exclusion criteria: History of trigeminal neurosensory disturbance. If genioplasty is included in treatment plan. History of diabetic, hypertension and kidney failure. those unwilling to sign informed consent form.

Intervention groups

We have two study groups in this trial: 1. The control group- are side of the mandible that will be treated with conventional sagittal split osteotomy. 2. The intervention group: The side of the mandible that will be treated by sagittal split osteotomy that will be assisted by computer

designed and manufactured surgical guide.

Main outcome variables

The inferior alveolar nerve neurosensory disturbance
Duration of osteotomy . Inferior alveolar nerve position after osteotomy . unfavorable fracture of mandible during osteotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150107020601N2**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

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aj-abbasi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2018-03-17, 1396/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study to assess feasibility of computer assisted designed and fabricated surgical guides in sagittal split osteotomy vs. conventional sagittal split osteotomy.

Public title

surgical guide in jaw surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18-35 years. Patients that has Mandibular sagittal split osteotomy in their treatment plan using virtual surgical planning osteotomy in their treatment plan using virtual surgical planning

Exclusion criteria:

The patients with a history of Trigeminal nerve Neurosensory disturbance If genioplasty is included in treatment plan Have medical condition associated with neuropathy (like Diabetic, Hypertension and Kidney problem Those unwilling to sign informed consent

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **9**

Randomization (investigator's opinion)

Randomized

Randomization description

We will have two study group, the side of mandibular ramus that will be treated by convention osteotomy (can be right or left) and the side that will be treated using the computer designed and manufactured surgical guide of same patient (the other side). For every patient the side of mandibular ramus will be selected by simple random sampling technique (tossing coin). The coin tossing will be used twice to select the side of mandible (right or left) and types of technique (surgical guide assist or conventional)

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study the participant, the outcome assessor and statistician will be blinded, they will not know what treatment is used for which side. The treatment will be registered using a code known only to investigator.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences Vice Chancellor for Research

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Approval date

2017-10-15, 1396/07/23

Ethics committee reference number

IR.TUMS.VCR.REC.1396.3722

Health conditions studied**1****Description of health condition studied**

Orthognatic surgery, feasibility of computer assisted designed and fabricated surgical guide in sagittal split ramus osteotomy

ICD-10 code

M26.03

ICD-10 code description

Mandibular hyperplasia

Primary outcomes**1****Description**

1. Inferior Alveolar nerve neurosensory disturbance

Timepoint

1. Neurosensory disturbance will be assessed at second week, first month and three month after operation.

Method of measurement

A. Quantitative neurosensory testing lower lip and chin 1. Direction of brush stroke using cotton 2. Two point discrimination using needle 3. Tactile threshold using Semmes-Weinstein (SW) monofilament . 4. Temperature awareness by using a tube filled hot water or ice B. Subjective neurosensory testing using a visual analogue scale (VAS).

Secondary outcomes

1

Description

Duration of osteotomy

Timepoint

Intraoperative

Method of measurement

minute

2

Description

unfavorable fracture

Timepoint

intraoperative

Method of measurement

yes/ no

Intervention groups

1

Description

Intervention group: The Mandibular ramus side for which computer assisted designed and fabricated surgical guide will be used will intervention group. y

Category

Treatment - Surgery

2

Description

Control group: The side of Mandible that will be treated with conventional sagittal split osteotomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital, Oral And Maxillofacial Surgery Ward

Full name of responsible person

Dr. Amir Jalal Abbasi

Street address

Sina Hospital Oral and Maxillofacial surgery ward,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Campus - Tehran University of Medical
Sciences Vice Dean for reasearch Affairs

Full name of responsible person

Mr. Izadyar

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Grant name

Fund for thesis of post graduate international student

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

International Campus - Tehran University of Medical
Sciences Vice Dean for reasearch Affairs

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

Tehran University of Medical Sciences

Full name of responsible person

Shimelis Megersa Gema

Position

Resident of Oral and Maxillofacial surgery

Latest degree

Bachelor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

We do not have a data to share

When the data will become available and for how long

We are responsible to share our finding till it will be
published as an article on journal.

To whom data/document is available

In cases an academican or academic institution
requested to use the finding of this work we are ready to
share

Under which criteria data/document could be used

We do not have different criteria

From where data/document is obtainable

Principal investigator

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

The person or academic institution who want to access
this data, will be confirmed that they are requesting the
data for academic purpose before sharing.

Comments

Thanks