Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Effects of preoperative imaging of inferior alveolar nerve canal with Cone Beam CT on neurosensory dysfunction following bilateral sagittal split ramus osteotomy in mandibular setback.

Protocol summary

Summary

The purpose of this study is to evaluate the relationship of imaging of the IAN canal with CBCT before surgery and neurosensory dysfunction after Bilateral Sagittal Split Ramus Osteotomy. In this clinical trial we will study 40 patients with mandibular prognathism which needed mandibular setback surgery. Plain radiographs included of orthopantograms and lateral cephalograms will take from all patients. In the study group we will take CBCT from the both sides of the ramus and mandibular body to the region of second molar . Surgical technique in all patients is BSSO with the Obwegeser-Dal Pont technique and modification of Hunsuck. Evaluation of neurosensory function of the IAN will be done subjective with a questioner of 5 point scaling after one week, 3 weeks, 3 months, 6 months and 12 months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052217798N1**
Registration date: **2014-08-07, 1393/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-07, 1393/05/16

Registrant information

Name

Hamidreza Mahaseni Aghdam

Name of organization / entity

Tehran Azad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 6440

Email address

dr_hamid_mahaseni@irimc.org

Recruitment status

Recruitment complete

Funding source

Tehran Azad University of Medical Sciences

Expected recruitment start date

2014-06-06, 1393/03/16

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of preoperative imaging of inferior alveolar nerve canal with Cone Beam CT on neurosensory dysfunction following bilateral sagittal split ramus osteotomy in mandibular setback.

Public title

Effects of preoperative imaging of lower jaw with bone scan on neurosensory dysfunction of the lip following mandibular surgery for setback

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria:patients with mandibular prognathism; movement lower than 7 millimeter; no difference in third molar relationship exclusion criteria: jaw asymmetry; pathologic condition related to inferior alveolar nerve; history of previous jaw surgery; neurosensory disturbances; medical conditions with systemic

neuropathy; need for genioplasty.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

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
local board of ethics and research method of Azad University of Medical Science

Street address
pasdaran street

City
tehran

Postal code

Approval date
2013-09-22, 1392/06/31

Ethics committee reference number
p/214/d

Health conditions studied

1

Description of health condition studied
neurosensory dysfunction of inferior alveolar nerve after bilateral sagittal split ramus osteotomy

ICD-10 code

ICD-10 code description

2

Description of health condition studied
inferior alveolar neurosensory dysfunction

ICD-10 code
G50.9

ICD-10 code description
Disorder of trigeminal nerve, unspecified

Primary outcomes

1

Description
dysfunction of inferior alveolar nerve

Timepoint
day 7 and months 1, 3, 6, 12

Method of measurement
subjective by queationer (five point scaling)

Secondary outcomes

empty

Intervention groups

1

Description
intervention: we will take Cone Beam CT imaging from inferior alveolar nerve canal before surgery.

Category
Prevention

2

Description
control group: we will take panoramic and lateral cephalometry and posterior anterior cephalometry before surgery

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Buali hospital

Full name of responsible person
hamidreza mahaseni aghdam

Street address
damavand street

City
tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Azad University of Medical Sciences

Full name of responsible person
Azad University of Medical Sciences

Street address
Buali Hospital, Damavand street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Azad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran Azad University of Medical Sciences,

Full name of responsible person

Hamidreza Mahaseni Aghdam

Position

resident

Other areas of specialty/work

Street address

Damavand street, Buali hospital

City

Tehran

Postal code

Phone

+98 21 3331 1106

Fax

Email

dr_hamid_mahaseni@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Azad University of Medical Sciences

Full name of responsible person

Hamidreza Mahaseni Aghdam

Position

resident

Other areas of specialty/work

Street address

Buali hospital, Damavand street

City

Tehran

Postal code

Phone

+98 21 3331 1106

Fax

Email

dr_hamid_mahaseni@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Azad University of Medical Sciences

Full name of responsible person

Hamidreza Mahaseni Aghdam

Position

resident

Other areas of specialty/work

Street address

Buali hospital

City

Tehran

Postal code

Phone

00

Fax

Email

dr_hamid_mahaseni@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty