

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Incidence of Inferior Alveolar Nerve (IAN) disturbance in Bilateral Sagittal Split Osteotomy (BSSO) in skeletal cl. II and cl. III patients by piezoelectric procedure as compared with conventional procedure.

Protocol summary

Study aim

The effects of conventional and piezoelectric surgery on incidence of Inferior Alveolar Nerve (IAN) disturbance in Bilateral Sagittal Split Osteotomy (BSSO)

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Skeletal cl. 2 and 3 patients who are candidate for BSSO surgery in the Bouali hospital are involved in this study. Piezoelectric and conventional osteotomies are going to be carried out on each side of the mandible by the same specialist. The function of sensory nerve (IAN) is going to be evaluated by 4 following tests: 1. light touch test 2. pin prick test 3. two point discrimination test 4- two moving point discrimination test, before surgery and post-operatively (7 days, 1, 3 months). Patients and examiners are blinded to the applied procedure which is allocated to each side of the mandible.

Participants/Inclusion and exclusion criteria

- Skeletal cl. II and cl. III patients who are candidate for BSSO (including criteria) - Patients who had experienced maxillofacial surgery (excluding criteria) - Patients who had any kind of systemic disease (excluding criteria)

Intervention groups

- Conventional osteotomy is a procedure in which burs and saws are used for cutting mandibular bone - Piezoelectric osteotomy is a procedure in which piezoelectric is used for cutting mandibular bone .

Main outcome variables

Inferior Alveolar Nerve disturbance following BSSO surgery: Any neurosensory changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180513039633N1**

Registration date: **2018-06-01, 1397/03/11**

Registration timing: **retrospective**

Last update: **2018-06-01, 1397/03/11**

Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Vahid Mesgarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2018-06-30, 1397/04/09

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-05-10, 1397/02/20

Trial completion date

empty

Scientific title

Incidence of Inferior Alveolar Nerve (IAN) disturbance in Bilateral Sagittal Split Osteotomy (BSSO) in skeletal cl. II

and cl. III patients by piezoelectric procedure as compared with conventional procedure.

Public title

Assessment of the incidence of Inferior alveolar nerve (IAN) disturbance in both conventional and piezoelectric procedure in Bilateral Sagittal Split Osteotomy (BSSO).

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Skeletal cl. II and cl. III patients that are candidate for BSSO surgery (BSSO : Bilateral Sagittal Split Osteotomy)

Exclusion criteria:

History of previous maxiofacial surgery History of systemic diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

Bilateral Sagittal split Osteotomy in Mandible

Actual sample size reached: **10**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Bilateral Sagittal split Osteotomy in Mandible

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were selected by envelopes shuffling simple randomization for each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Just as the patients, the examiners of the mentioned tests which are going to be carried out will be blinded to the type of the applied procedures (piezoelectric or conventional)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran Azad Dental University

Street address

No. 4, Neyestan Alley, Pasdaran street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.IAU.DENTAL.REC.1396.14

Health conditions studied

1

Description of health condition studied

Inferior Alveolar Nerve (IAN) preturbation

ICD-10 code

G97.8

ICD-10 code description

Other intraoperative and postprocedural complications and disorders of nervous system

Primary outcomes

1

Description

light touch sensation

Timepoint

Before intervention, and 7 , 30 and 90 days after intervention

Method of measurement

Visual

2

Description

Pin-Prick test (Needle test)

Timepoint

Before intervention, and 7 , 30 and 90 days after intervention

Method of measurement

Visual

3

Description

Weber Test (Two point discrimination)

Timepoint

Before intervention, and 7 , 30 and 90 days after intervention

Method of measurement

Visual

4

Description

moving 2 point discrimination

Timepoint

Before intervention, and 7 , 30 and 90 days after intervention

Method of measurement

Visual

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: BSSO surgery through piezoelectric procedure will be performed on one side of the mandible of 10 patients randomly by "Piezosurgery"; Mectron Medical Technology, Crasco, Italy. In all cases, the setting will be "cortical bone" and in accordance with the developer's recommendations. The water pump will be set at level 5 , which equals 60 mL per minutes.

Category

Treatment - Surgery

2

Description

Control group: BSSO surgery through conventional method will be performed by the means of burs and saws on one side of the mandible of 10 patients randomly.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital

Full name of responsible person

Dr. Amir Ijadi

Street address

Damavand Street , Imam Hossein Sq.,Tehran , Iran ,
Booali hospital

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admin@bouali-hospital.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Afshin Harraji

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No. 4 , 9th Neyestan Alley, Pasdaran St., Tehran , Iran

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Web page address

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Hassan Mesgari

Position

Resident

Latest degree

Medical doctor

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

All of the information are potentially accessible after making unknown personal identities.

When the data will become available and for how long

Access will be allowed within 6 months after publishing

To whom data/document is available

Academic Researchers

Under which criteria data/document could be used

In any individual case please contact correspond writer .

From where data/document is obtainable

Dr. Vahid Mesgarzadeh : 00989121302563
V_mesgarzadeh@dentaliau.ac.ir Dr. Hassan Mesgari :
00989126216965 kmesgari@gmail.com

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

First an E-mail should be sent to the correspond writer , after evaluating the request in the research committee , approved information will be given to the requester.

Comments