

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of The Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Maximum Mouth Opening (MMO) after Orthognathic Surgery

Protocol summary

Study aim

Evaluation of the Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Maximum Mouth Opening (MMO) after Orthognathic Surgery

Design

Two arm parallel group randomized clinical trial on 82 patients

Settings and conduct

This study takes place in Imam Hossein hospital . Patients are divided into intervention and control groups by the use of accidental blocks classified by age and sex . The intervention group goes is underwent Transcutaneous Electro Nerve Simulation (TENS) physiotherapy 3 sessions a week for a month starting the day after surgery. other post operative protocols are the same in both intervention and control groups. Maximum Mouth Opening (MMO) will be measured once before surgery as a baseline and then 1 and 6 month after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Skeletal Class III patients who are candidates for Lefort I maxillary advancement and Bilateral Sagittal Split Osteotomy mandibular set back with Dalpont method exclusion criteria : Pathologic lesions around surgical areas History of limitation in jaw movements Drug use due to psychological problems History of jaw fractures Previous jaw surgery If maxillary advancement or mandibular setback is more than 6 millimeters Surgeries longer than 6 hours Bad split and on-the-job accidents Simultaneous genioplasty performing Patients who need other maxillofacial surgery after orthosurgery Patients with cardiac pacemaker Epilepsy patients Patients with a history of Cerebro-Vascular Accident

Intervention groups

The intervention group takes TENS physiotherapy sessions. This patients will have 12 physiotherapy sessions ; 3 times a week for one month which starts the day after surgery. other post operative protocols are the

same in both intervention and control group.

Main outcome variables

Maximum Mouth Opening (MMO) after Orthognathic Surgery following "TENS physiotherapy"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211205053279N2**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Mostafa Alam

Name of organization / entity

Country

Iran (Islamic Republic of)

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mostafa_alam@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-03, 1400/12/12

Expected recruitment end date

2023-03-03, 1401/12/12

Actual recruitment start date

empty

week for a month starting the day after surgery, 12 sessions in total. TENS, or transcutaneous electrical nerve stimulation, is a category of electrical modalities that is used in physiotherapy to treat pain, inflammation, muscle spasms, weakness, and other neuromuscular disorders. The electrodes of the device are placed on the healthy skin in the surgical area bilaterally, high and low frequency stimulations start in standard parameters in terms of frequency, duration and pulsed width.

Traditional TENS requirements: Frequency of 150Hz, pulse width of 20 microseconds, pulse intensity starts from 10-30 mA and will be adjusted exclusively for each individual to the maximum tolerance threshold (but to the extent that the patient is comfortable). The pulses are Quadratic Biphasic Symmetrical and the modulation of up to 50% of the frequency variation and time of each session will be 45 minutes. Maximum Mouth Opening (The distance between the edges of the upper and lower incisors) will be measured by a digital caliper once before surgery as a baseline and then 1 and 6 months after surgery, recording and evaluation will be performed.

Category

Rehabilitation

2

Description

Control group: no interventions. Maximum Mouth Opening (The distance between the edges of the upper and lower incisors) will be measured by a digital caliper once before surgery as a baseline and then 1 and 6 months after surgery. Recording and evaluation will be performed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Mostafa Alam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mostafa Alam

Position

Assistant Professor

Latest degree

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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

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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