

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The Effect of platelet-rich fibrin on nerve regeneration after bilateral sagittal split osteotomy of the mandible

Protocol summary

Summary

The purpose of this study is to assess the effect of platelet-rich fibrin on nerve regeneration after bilateral sagittal split osteotomy. The studied population in this randomized clinical trial in a parallel method, is 30 patients with class II or class III skeletal deformity who are candidate for mandibular osteotomy for correction of mandibular deformity. Patients with a history of previous trauma to the jaw; Patients who have a history of previous surgery mandibular osteotomy; patients who had genioplasty in addition to mandibular osteotomy will be excluded from the study. The sample size will be 60 bilateral sagittal split osteotomies in two groups (each group has 30 osteotomies). 20 cc blood was taken from each patient. Then blood is centrifuged in 1800 rpm. Platelet rich plasma is mixed with 1 cc Gloconate calcium to prepare platelet rich fibrin. Platelet rich fibrin will be used in one osteotomy side (group 1) during surgery and another side will be considered as a control side (group 2). Selection of study side will be based on randomization. Evaluation of lower lip anesthesia is performed at intervals of 6 months and a year. Evaluation of anesthesia will be performed by the third observer without informing of the control or treatment side. All the patients are unaware of the treatment and control side. All surgeries are done by one surgeon and one surgical and fixation procedure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122631571N1**
Registration date: **2017-09-05, 1396/06/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-05, 1396/06/14

Registrant information

Name

Reza Tabrizi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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pourdanesh_f@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

The study is supported by Research Department of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2018-09-30, 1397/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of platelet-rich fibrin on nerve regeneration after bilateral sagittal split osteotomy of the mandible

Public title

The effect of Platelet-rich fibrin on anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with class II or class III skeletal

deformity who are candidate for mandibular osteotomy for correction of mandibular deformity. exclusion criteria:patients who use anti deppresant drugs;Patients with a history of previous trauma to the jaw;Patients who have a history of previous surgery mandibular osteotomy;patients who had genioplasty in addition to mandibular osteotomy.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

2

Registry name

Clinicaltrial.gov

Secondary trial Id

NCT03159338

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

velenjak,daneshju Blv.

City

tehran

Postal code

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IR.SBMU.RIDs.REC.1395.249

Health conditions studied

1

Description of health condition studied

anesthesia caused by sagittal osteotomy in patients with class II and III deformity

ICD-10 code

S04.3

ICD-10 code description

Injury of trigeminal nerve

Primary outcomes

1

Description

amount of displacement of the jaw

Timepoint

during surgery

Method of measurement

mm

Secondary outcomes

1

Description

lower lip anesthesia

Timepoint

Every 6 months and a year

Method of measurement

Based on distance of two detectable points on the the lip in mm.

Intervention groups

1

Description

In intervation group(the studied side)platelet-rich fibrin produced from patient's blood is used.20 cc of the patient blood is centrifuged for 14 minutes at a speed of 28,000 rpm. The middle solution between plasma and RBC is separated after a 5 minute respite and is mixed with 1cc calcium gloconate.A gelatinous substance is prepared after 15 minutes.This substance is placed between two osteotomy pieces on Inferior Alveolar Nerve before the fixation .

Category

Treatment - Drugs

2

Description

In control group(the opposite side) fixation is done

without any substance.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Dr. Reza Tabrizi

Street address

Arabi St., Daneshju Blv., Velenjak

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

6th floor, Building No. 2, Shahid Beheshti University of
Medical Sciences, Daneshju Blv., Velenjak

City

Tehran

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Reza Tabrizi

Position

OMFS Microvascular Fellowship

Other areas of specialty/work

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Contact

Name of organization / entity

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Şaba Jafari

Position

Student

Other areas of specialty/work

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j.saba92@yahoo.com

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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