

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The effect of Low level laser in biomaterial used in maxillary sinus graft (histological and Radiological examination) a randomized controlled clinical trial

Protocol summary

Summary

The aim of study: Evaluation of Low level laser effect on biomaterial (FDBA+PRF) used in maxillary sinus augmentation. Study design: This study is designed as a split mouth; it means that in all participants in the study, one side will be treated as a control group randomly and opposite side as an intervention group. All patients will undergo bimaxillary sinus lift surgery and in both sides (either control group or intervention groups) will be used FDBA and PRF as biomaterials for sinus floor augmentation. After completion of the surgery, on the intervention side will be used low level laser (LLL) for 30 seconds in the times of immediately after the surgery and third and fifth days after surgery. In this randomized clinical trial will be selected 19 patients of 30-80 year-old that major inclusion criteria is severe atrophy in posterior of maxillary: either complete edentulous or bilateral posterior edentulous. The major exclusion criteria of patients from study are the existence of systemic diseases and pathological lesions in the maxillary sinus. CBCT and Panoramic radiographs will be supplied from all of patients before surgery. Study Outcomes: After 5 months from the sinus surgery, at first CBCT will be taken for bone density assessment of surgery area (according to Hansfield unit) and then will be taken biopsy from certain areas and samples will be sent to histological laboratory for histologic evaluation of percentage of new bone formation and the remaining biomaterials.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012410155N3**

Registration date: **2016-02-22, 1394/12/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-22, 1394/12/03

Registrant information

Name

Mohammad Taghi Chitsazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

chitsazm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Gingival and Dental Research Center of Tabriz Dentistry Faculty

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Low level laser in biomaterial used in maxillary sinus graft (histological and Radiological examination) a randomized controlled clinical trial

Public title

The effect of Low level laser in biomaterial used in

maxillary sinus graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The existence of bilaterally partial edentulous in maxillary posterior region or complete edentulous in maxilla; Height of the remaining bone between the floor of sinus and alveolar crest be less than 5mm Exclusion criteria: Smokers; pregnant women ; pathological symptoms or cystic lesions in the sinus ; acute and chronic inflammatory disease of sinus; benign and malignant tumors in sinus ; uncontrolled systemic diseases ; the existence of untreated periodontal disease

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **19**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Univrsity of Tabriz Medical Science

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences

City

TABRIZ

Postal code

Approval date

2016-01-20, 1394/10/30

Ethics committee reference number

tbzmed.rec.1394.922

Health conditions studied

1

Description of health condition studied

Resorption of alveolar ridge in the maxillary posterior region

ICD-10 code

K08.2

ICD-10 code description

Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description

The newly formed bone

Timepoint

5 months after grafting

Method of measurement

Histologic examination and measurements through the via software motic images plus v2.0

2

Description

Evaluation of The newly formed bone density

Timepoint

5 months after grafting

Method of measurement

By CBCT and NNT viewer Version21 software

Secondary outcomes

empty

Intervention groups

1

Description

The sinus floor of control group will be augmented with lateral window sinus lift surgical technique by using biomaterials (allograft + PFR)

Category

Treatment - Surgery

2

Description

Intervention group: Surgical technique and biomaterials is similar to the control group, with the difference that immediately after the surgery and the third and fifth days after surgery, low level laser (diode laser "BioLase", 980nm, 0.5 W) will be lighted on surgery area.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Dr Chitsazi

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences

City

Tabriz

+98 41 3335 5968

Fax**Email**

a_h_dehgani@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Dentistry, Tabriz University of Medical Science

Full name of responsible person

Dr MohamadTagi Cheitsazi

Position

Associated Prof

Other areas of specialty/work**Street address**

Faculty of Dentistry, Golghast Ave

City

Tabriz

Postal code

5166614711

Phone

+98 41 3335 5968

Fax**Email**

chitsazm@tbzmed.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gingival and Dental Research Center of Tabriz dentistry Faculty

Full name of responsible person

Dr Shahriar Shahi

Street address

Faculty of Dentistry, Tabriz University of Medical Sciences TABRIZ

City

Tabriz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gingival and Dental Research Center of Tabriz dentistry Faculty

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**

Faculty of Dentistry

Full name of responsible person

Dr Alihossein Dehghani

Position

Resident of Periodontics

Other areas of specialty/work**Street address**

Faculty of Dentistry, Golgasht Ave.

City

Tabriz

Postal code**Phone****Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Dentistry

Full name of responsible person

Dr Alihossein Dehghani

Position

Resident of Periodontics

Other areas of specialty/work**Street address**

Faculty of Dentistry, Golghast Ave

City

Tabriz

Postal code

5166614711

Phone

+98 41 3335 5968

Fax**Email**

a_h_dehgani@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