Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 asa split mouth; it means that in all participants in the study,one side will treated asa control group randomly and opposite side as an intervention group. All patients will undergone bimaxillary sinus lift surgery and in both sides (either control group or intervention groups)will be used FDBA and PRF as biomaterials forSinus floor Augmentation.After completion of the surgery, on the intervention sidewill 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 inposteriorof maxillary؛either complete edentulous or bilateral posterior edentulous. The major exclusioncriteria of patients from study are the existence of systemic diseases and pathological lesions in the maxillary sinus. CBCT and Panoramic radiographs will be supplying from all of patientsbefore 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 laboratoryfor 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)

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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
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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
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Faculty of Dentistry, Tabriz University of Medical Sciences TABRIZ
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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

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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