

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

A comparative study of autogenous bone graft use with and without low-level laser therapy in the treatment of the two and three wall intrabony periodontal defects

Protocol summary

Summary

The purpose of this study was to compare the use of autogenous bone alone and in combination with Low-level laser therapy (LLLT) in the treatment of two and three wall periodontal intrabony defects in human. Study population: Referred patients to the periodontics department of Tabriz university of medical sciences from May 2011 to December 2011. Sample size: 15. Inclusion criteria: Patient with moderate to severe generalized chronic periodontitis with at least two similar infra-bony defects in the interproximal region with probing depth greater or equal to 5 mm and lesion depth of equal to or greater than 3 mm. Exclusion criteria: Presence of systemic disease interfering with periodontal surgery or healig; smoking. Intervention and timing: Low-level laser therapy during pocket regenerative therapy. Primay outcome: Clinical attachment level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207019121N2**

Registration date: **2012-07-22, 1391/05/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-22, 1391/05/01

Registrant information

Name

Mehrnaz Sadighi Shamami

Name of organization / entity

Dental faculty, Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dental faculty, Tabriz university of medical sciences

Expected recruitment start date

2011-05-01, 1390/02/11

Expected recruitment end date

2012-12-04, 1391/09/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of autogenous bone graft use with and without low-level laser therapy in the treatment of the two and three wall intrabony periodontal defects

Public title

The effect of bone graft use with low-level laser therapy in the treatment of periodontal disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Full mouth plaque index (FMPI) \leq 20%; the percentage of the areas which are bleeding within 30 seconds after the probe be less than or equal to 20%; in the radiographic assessment which was confirmed with bone sounding, each patient has at least one pair similar infra-bony defects in the interproximal region with probing depth greater or equal to 5 mm and

lesion depth of equal to or greater than 3 mm. Exclusion criteria: presence of systemic disease interfering with periodontal surgery or healing; smoking; trauma from occlusion; prolonged use of drugs interfering with bone metabolism; pregnancy and lactation; antibiotic use during study or in the past 6 months.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

15 patients with moderate to severe chronic periodontitis with bilateral intrabony defects are included. In a split mouth study design, 15 defects are treated by OFD and autogenous bone while others receive low-level laser therapy as an adjunct treatment. A GaAlAs diode laser is used. Soft and hard tissue variables are recorded relative to an acrylic stent at baseline and after 3 months.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz university of medical sciences ethic committee

Street address

Tabriz university of medical sciences, Golgasht avenue

City

Tabriz

Postal code**Approval date**

2012-06-09, 1391/03/20

Ethics committee reference number

9147

Health conditions studied**1****Description of health condition studied**

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic pericoronitis

Primary outcomes**1****Description**

bone fill of the intrabony defect

Timepoint

baseline, three months later

Method of measurement

UNC-15 probe

Secondary outcomes**1****Description**

clinical attachment level

Timepoint

baseline, 3 months

Method of measurement

UNC 15

Intervention groups**1****Description**

Control group: Regenerative surgery under local anesthesia of Lidocaine 2% with epinephrine 1/80000- sulcular incision in buccal and lingual aspects and debridement of the lesion with hand instruments and ultrasonic devices- use of autogenous bone graft in the bone defect.

Category

Treatment - Surgery

2**Description**

Intervention in test group: Regenerative surgery under local anesthesia of Lidocaine 2% with epinephrine 1/80000- sulcular incision in buccal and lingual aspects and debridement of the lesion with hand instruments and ultrasonic devices- use of autogenous bone graft in the bone defect and laser use following suturing with the following parameters: GaAlAs laser with continuous wave and 40 mw power and energy fluence of 4 J/cm² and total energy of 16 J/cm² with 1 cm distance from the covering soft tissue.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty, Tabriz university of medical sciences

Full name of responsible person

Mehrnoosh Sadighi

Street address

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Dr. Mohamadreza Rashidi

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vice-chancellor for research, 2nd floor, administrative building of Tabriz university of medical sciences, Goltasht avenue, Abresan square

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz dental faculty

Full name of responsible person

Dr Mehrnoosh Sadighi

Position

post graduate student

Other areas of specialty/work

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Mehrnoosh Sadighi

Position

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Other areas of specialty/work

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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