

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of Effect of Light Emitting Diode (LED) on the Allograft Bone after the Open Sinus Lift (A Randomized clinical trial study)

Protocol summary

Study aim

Light Emitting Diode (LED) phototherapy has been used in some medical specialties because of its probable bio-stimulatory effect on biological tissues. However, Low Level Laser Therapy (LLLT) and LED phototherapy applications are still place of controversies because of different results in literature. Just a few studies have worked on the effect of phototherapy on bone stimulation clinically. So, the aim of this in vivo study was histological evaluation of quantity and maturational quality of the newly formed bone in the human maxillary sinuses after LED phototherapy.

Design

After 6 months, the sinus graft sites were re-opened to insertion of dental implants and bony biopsies were taken simultaneously. The specimens were routinely processed and colored with Hematoxylin and Eosin staining (H & E) and assessed by light microscope consequently.

Settings and conduct

The study is double blind. The samples were randomly divided into two groups by coin.

Participants/Inclusion and exclusion criteria

Exclusion criteria consist of smokers, having chronic sinusitis, diabetes, history of cancers and Bisphosphonate consumption and not willing to use LED device. Inclusion criteria do not include patients with chronic sinus disease, chronic bone disease, have no history of surgery. Do not have diabetes. Informed consent form of the company to sign the research.

Intervention groups

Forty patients were randomly divided into 2 groups (n=20). Group A received LED phototherapy (Biolum Ltd, Vancouver, Canada) with continuous wave length of 620 nm, 20 min/day for 21 days, after sinus lifting procedure. Group B was chosen as non-radiated controls.

Main outcome variables

Use of LED after surgery, bone maturity, osteoporosis, inflammation rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180222038827N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Mahnaz Arshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2227 3471

Email address

Arshad-m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effect of Light Emitting Diode (LED) on the Allograft Bone after the Open Sinus Lift (A Randomized clinical trial study)

Public title
Evaluation of Effect of Light Emitting Diode (LED) on the Allograft Bone after the Open Sinus Lift (A Randomized clinical trial study)

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Have no chronic sinus disease There is no chronic bone marrow disease There is no history of surgery in the area Do not have diabetes Knowingly sign the consent form of the company in the research. Have no history of radiotherapy and chemotherapy Maxillary premolars edentulism
Exclusion criteria:
 Smoking Chronic sinus disease Diabets History of cancer Consumption ofBisphosphonates Failure to use LED device

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly assigned to a number ranging from 1 to 40. The number of individuals in the case and paired numbers were in the control group, each group containing 20 patients

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the pathologist examines the histology of the specimens and the surgeries that have undergone the surgical procedure and the sampling have been kept blind.

Placebo
Not used

Assignment
Parallel

Other design features
none

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tehran University of Medical Sciences
Street address
 Unit 9, 3th Floor, Number 3, first Alley, Sanjabi Street, Madar Square, Mirdamad Street, Tehran, Iran
City
 Tehran
Province
 Tehran
Postal code
 19119-33963
Approval date
 2018-02-24, 1396/12/05
Ethics committee reference number
 IR.TUMS.REC.1394.1181

Health conditions studied

1

Description of health condition studied
edentulism

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maxillary premolar missing

Timepoint
Group A received LED phototherapy (Biolux Ltd, Vancouver, Canada) with continuous wave length of 620 nm, 20 min/day for 21 days, after sinus lifting procedure. After 6 months, the sinus graft sites were re-opened to insertion of dental implants and bony biopsies were taken simultaneously.

Method of measurement
A blind examiner (maxillofacial pathologist) analyzed each sample with a light microscope. In histological evaluations of these cases, following items were examined and graded as mentioned below: Degree of inflammation: defined as the following numbers: 1 = absence of inflammation, 2 = moderate inflammation and 3 = severe inflammation. Formation and bone quality: defined as the following numbers: 1 = connective tissue containing blood vessels, fibroblasts, macrophages, collagen fibers, 2 = dense connective tissue with the presence of large number of cells that differentiate into bone tissue which represents the initiation of bone formation, 3 = formation of new bone tissue, dense connective tissue, 4 = obvious bony tissues. The density of collagen fibers (maturation): it defined as the following numbers: 1 = absence of collagen fibers, 2 = average density of collagen fibers, 3 = high density of collagen fibers without a regular structure (assessed by using polarized light), 4 =

extreme density of collagen fibers with a definite structure (assessed by using polarized light) based on a pathologist's judgment after viewing all the samples at ×100 magnification.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sinus Lifting and LED

Category

Treatment - Devices

2

Description

Control group: Sinus lifting

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

dental implant Center, Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Arshad

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mahnazarshad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Gholamreza Shirani

Street address

North Amir Abad, not reaching Hakim exit, Tehran

Faculty of Dentistry, Dental Implant Center

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8835 1178

Email

ghr.shirani@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Arshad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

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Latest degree

Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data has subscription capability.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

all people

Under which criteria data/document could be used

none

From where data/document is obtainable

email to dr. Arshad

What processes are involved for a request to access data/document

none

Comments