Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Enamel Matrix Derivatives (EMD) to EMD/Decalcified Freezed Dried Bone Allograft (DFDBA) in the Treatment of Human Intrabony Periodontal Defects: A Controlled Clinical Trial With 6 Month Re-entry

Protocol summary

Summary

The aim of this study was to compare the enamel matrix derivative (EMD) alone to EMD combined with decalcified freezed dried bone allograft (EMD/DFDBA) in the treatment of human periodontal defects. Using a randomized split-mouth design, 18 paired intrabony defects were surgically treated either with EMD (EMD group) or EMD+DFDBA (EMD/DFDBA group). Surgical reentries were performed 6 months after initial surgery .A wilcoxon signed-rank test and Mann –whitney U test were used to compare inter and intra group changes (respectively) in clinical probing depth (CPD), clinical attachment level (CAL), gingival recession (GR), bony defect fill (DF), crestal resorption(CR) and defect resolution (DR)between baseline and 6 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020710501N2**
Registration date: **2013-03-22, 1392/01/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-03-22, 1392/01/02

Registrant information

Name

Nader Abolfazli

Name of organization / entity

Departyment of periodontics, Tabriz faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

abolfazli@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of medical sciences

Expected recruitment start date

2007-03-20, 1385/12/29

Expected recruitment end date

2008-03-19, 1386/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Enamel Matrix Derivatives (EMD) to EMD/Decalcified Freezed Dried Bone Allograft (DFDBA) in the Treatment of Human Intrabony Periodontal Defects: A Controlled Clinical Trial With 6 Month Re-entry

Public title

Treatment of intrabony defects

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were the presence of paired interproximal 2 or 3 wall vertical defects ≥3mm deep (distance between alveolar crest and base of the defect in intraoral periapical radiography) along with an interproximal probing depths ≥5.0 mm following initial

non-surgical therapy. The patient exclusion criteria consisted of : 1) known systemic diseases and/or drug therapy known to interfere with wound healing; 2) compromised immune system; 3) pregnancy and\ or lactation; 4) cigarette smoking; 5) using systemic antibiotics or having received antibiotic therapy in the last 3 months; and 6) O´Leary plaque score>20%.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **18**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of medical sciences

Street address
Golgasht AVE

City
Tabriz

Postal code
5165685471

Approval date
2012-12-31, 1391/10/11

Ethics committee reference number
91162

Health conditions studied

1

Description of health condition studied
periodontal disease

ICD-10 code
K05.3

ICD-10 code description
Chronic periodontitis

Primary outcomes

1

Description
Bony defect fill

Timepoint
Baseline and 6 month later

Method of measurement
periodontal probe

2

Description
Bony defect fill

Timepoint
Baseline and 6 month later

Method of measurement
periodontal probe

Secondary outcomes

1

Description
Clinical Attachment level

Timepoint
baseline and 6 month later

Method of measurement
periodontal probe

2

Description
Gingival recession

Timepoint
baseline and 6 month later

Method of measurement
periodontal probe

3

Description
clinical probing depth

Timepoint
baseline and 6 month later

Method of measurement
periodontal probe

Intervention groups

1

Description
Using EMD alone in the treatment of intrabony defects (control group)

Category
Treatment - Surgery

2

Description

Using EMD /DFDBA in the treatment of intrabony defects (Test group)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of medical sciences

Full name of responsible person

Nader Abolfazli

Street address

Tabriz University of medical sciences

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of medical sciences

Full name of responsible person

Alireza Ostad Rahimi

Street address

No 2, Central building , Daneshgah street

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

Dental faculty, Tabriz University of medice sciences

Full name of responsible person

Nader Abolfazli

Position

Associated professor

Other areas of specialty/work

Street address

Dental faculty,Tabriz University of medice sciences

City

Tabriz

Postal code

Phone

+98 41 1335 5965

Fax

Email

abolfazli@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz dental faculty

Full name of responsible person

Nader Abolfazli

Position

periodontist

Other areas of specialty/work

Street address

Tabriz dental faculty, periodontics department

City

Tabriz

Postal code

Phone

+98 41 1335 5965

Fax

Email

abolfazli@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz dental faculty

Full name of responsible person

Nader Abolfazli

Position

Associated professor

Other areas of specialty/work

Street address

Tabriz dental faculty

City

Tabriz

Postal code

Phone

+98 41 1335 5965

Fax

Email

abolfazli@tbzmed.ac.ir

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