Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effects of amniotic membrane with collagen membrane in guided bone regeneration in dental implant surgery: a randomized clinical trial

Protocol summary

Study aim
Comparison of the effect of amniotic membrane and collagen membrane on guided bone regeneration in dental implant surgery

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, simple randomization using random number table and randomization.com site and opaque sealed envelope with random sequence

Settings and conduct
The study was performed at the implant section of Mashhad Dental School clinic. Patients were randomly divided into two groups and implant treatment was performed. After 3-4 months, the implant stability was assessed by a researcher unaware of the used membrane.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the implant department of the Mashhad dental school clinic; implant candidate; having a 3-wall intrabony defect. Non-inclusion criteria: Individuals with systemic disease; presence of local factors that prevent natural healing

Intervention groups
Control group (Membrane collagen group): The bone defect was filled with bone graft (Cerabone, GmbH, Germany) before placing the implant (Biohorizons, BioHorizons IPH) and then covered with collagen membrane with a size of 2cm.1/5cm (Jason membrane, bottis, Germany). Intervention group (Membrane amniotic group): The bone defect was filled with bone graft (Cerabone, GmbH, Germany) before placing the implant (Biohorizons, BioHorizons IPH), but then it was covered by amniotic membrane (AmniPatch, TRC, Iran).

Main outcome variables
Implant osteointegration; Implant success rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201012049004N1**
Registration date: **2020-11-01, 1399/08/11**
Registration timing: **retrospective**

Last update: **2020-11-01, 1399/08/11**
Update count: **0**

Registration date
2020-11-01, 1399/08/11

Registrant information

Name
Saba Manteghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3601 2976

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manteghis931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
2018-11-25, 1397/09/04

Actual recruitment end date
2019-12-22, 1398/10/01

Trial completion date
2020-04-20, 1399/02/01

Scientific title
Comparison of effects of amniotic membrane with collagen membrane in guided bone regeneration in dental implant surgery: a randomized clinical trial

Public title
The effect of amniotic membrane and collagen membrane in guided bone regeneration in implant treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient referred to the implant department of the Mashhad Dental School Candidate for dental implant Having 3-wall intrabony defect
Exclusion criteria:
The presence of any kind of systemic diseases The presence of any kind of local factors that might impede the natural healing process of the tissue

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **20**
Actual sample size reached: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization was used using a random number table taken from randomization.com which consisted of disordered numbers and even numbers were used for the intervention group and odd numbers for the control group. For concealment, based on the sample size, 20 opaque envelopes were prepared and a card containing a random sequence was inserted in which the random sequence was created by the method described. Cards with random sequences were placed in order. In order to maintain a random sequence, numbering was done in the same way on the outer surface of the envelopes. Finally, the envelopes were sealed and placed inside a box.Based on the order of entry of eligible participants in the study, one of the envelopes of the order was opened and the assigned group of that participant was revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient was informed verbally and in writing through a written consent letter that one of the two membranes examined in the study would be used, but ultimately the patient and the researcher were unaware of the type of membranes used in implant surgery.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences; Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948959

Approval date
2016-06-01, 1395/03/12

Ethics committee reference number
IR.MUMS.SD.REC.1395.123

Health conditions studied

1

Description of health condition studied
3-wall intrabony defects in jaws

ICD-10 code
M27.61

ICD-10 code description
Osseointegration failure of dental implant

Primary outcomes

1

Description
The amount of bone formed on the implant

Timepoint
Intervals of 12 weeks (in the mandible) and 16 weeks (in the maxilla) after stage 2 surgery

Method of measurement
Clinically determined by the percentage of exposed implant threads in the second stage of surgery

2

Description
Implant success rate

Timepoint
At intervals of 12 weeks (in the mandible) and 16 weeks (in the maxilla) after surgery

Method of measurement
Implant success rate is determined by reflection frequency analysis (RFA) test using Osstell Mentor

(Integration Diagnostics Ltd., Göteborg, Sweden) as well as the application of a reverse torque force of 35 N / cm by the reverse mode of the implant surgery engine and angle 20: 1, It is measured during the second stage of implant surgery. In the osstell mentor device, according to osseointegration a number between 1 and 100 is shown. This number is the Implant Stability Quotient(ISQ) . The higher the ISQ displayed by the device, the higher the degree of integration. In evaluation by reverse torque force, success is expressed as stable and implant failure as unstable.

Secondary outcomes

1

Description
Periodontal tissue healing rate on implant
Timepoint
At 1, 2 and 4 weeks after surgery
Method of measurement
periodontal tissue healing rate is expressed as the absence of membrane and bone graft exposure(A), only membrane exposure (B), or membrane and bone graft exposure (C).

2

Description
The incidence of infection in the surgical area
Timepoint
At 1, 2 and 4 weeks after surgery
Method of measurement
The incidence of infection in the area is measured and expressed as the presence (+) or absence (-) of infection according to the symptoms of infection in the area (swelling, pain, persistent erythema and secretion of pus).

3

Description
Patients' postoperative pain
Timepoint
In the first, third and tenth day after surgery
Method of measurement
The amount of pain after surgery of the patient is recorded using a VAS scale in a questionnaire designed for this purpose. In this scale, the amount of pain is classified from 0 to 10 based on the severity of pain.0 is the absence of pain and 10 is the presence of the most severe pain possible.

Intervention groups

1

Description
Intervention group (amniotic membrane group): The bone defect was filled with bone graft (Cerabone, GmbH, Germany) before placing the implant (Biohorizons, BioHorizons IPH),then it was covered with amniotic membrane (AmniPatch, TRC, Iran).finally the flap was initially sewn on the membrane without hatching the periosteum. Patients were prescribed antibiotics for up to 5 days (clindamycin 300 mg four times a day), analgesics for up to 3 days (ibuprofen 400 mg three times a day) and chlorhexidine 0.12% mouthwash twice a day for 2 weeks.
Category
Treatment - Surgery

2

Description
Control group (collagen membrane group): The bone defect was filled with bone graft (Cerabone, GmbH, Germany) before placing the implant (Biohorizons, BioHorizons IPH) and then covered with collagen membrane (Jason membrane, bottis, Germany) with a size of 2cm*1.5cm . Finally the flap was initially sewn on the membrane without hatching the periosteum. Patients were prescribed antibiotics for up to 5 days (clindamycin 300 mg four times a day), analgesics for up to 3 days (ibuprofen 400 mg three times a day) and chlorhexidine 0.12% mouthwash twice a day for 2 weeks.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental clinic, affiliated to Mashhad University of Medical Sciences
Full name of responsible person
Hassan Hosseinpour Jajarm
Street address
Mashhad University of Medical Sciences; Azadi square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahdi Gholami
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
Saba Manteghi
Position
student
Latest degree
A Level or less
Other areas of specialty/work
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No.75, Soroush 4 street, Vakil-abad boulevard
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
was not anticipated in the proposal
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available

Data Dictionary	No - There is not a plan to make this available