

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

comparison between AlloDerm and Amniotic membrane as covering material for healing post operative wounds in Clark Vestibuloplasty

Protocol summary

Summary

Subjects , referred from Department of Prosthodontics, will be recruited for this study. informed consent, approved by research ethical board of Mashhad University of Medical Science, will be signed by each patient prior to surgical procedure. The inclination of the anterior wall of the mandible body will be assessed by lateral cephalogram. In addition, panoramic radiography will be used for alveolar bone height evaluation. Firstly, the labial vestibular depth was increased 1 centimeter by scrapping the cast. Next, considering the inclination of the anterior wall of the body of the mandible, the splint was created, finished and polished. Two hours prior to the vestibuloplasty, all subjects will received preoperative dose of 2 g amoxicillin orally and continued to take 0.5 g of antibiotics three times daily for 7 days. After receiving local anesthesia of 2% lidocaine plus 1/100000 epinephrine, a flap will be released from underlying periosteum via a horizontal incision through mucogingival border, extending from right to left premolar area. The flap was then apically positioned 10 mm and will be sutured with 4-0 silk to the periosteum. In each patient the right and left exposed periosteum will be covered by Cryopreserved Human Amniotic Membrane (AM) and acellular dermal matrix (ADM) respectively. The splint, will be lined with soft liner to establish minimal dead space creation, fixed with two bone screws. After removal of the splint and the fixation screws on postoperative day 7, all participants will be followed up after 7 days, 2 weeks, 4 weeks to assess vestibular depth. specimen will be obtained from graft margins for evaluating CD31 and CD68 positive cells migration. All data will be analysed by SPSS 18 software. In this study, subjects, surgeon, examiner, and data analyser will be blinded to the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082835160N1**

Registration date: **2017-08-28, 1396/06/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-28, 1396/06/06

Registrant information

Name

Mahdi Gholami

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 0736

Email address

gholamimh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of Medical Science

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between AlloDerm and Amniotic membrane as covering material for healing post operative wounds in

Clark Vestibuloplasty

Public title
Effect of alloderm and amniotic membrane as covering materials for healing oral wounds.

Purpose
Treatment

Inclusion/Exclusion criteria
1. Complete Edentulism in lower jaw. 2. Alveolar bone resorption in mandible 3. Having at least 2 mm of residual bone in lower jaw

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Randomization will be performed by coin flip

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Science

Street address
Azadi Square- Dentistry Faculty

City
Mashhad

Postal code

Approval date
2017-05-17, 1396/02/27

Ethics committee reference number
IR.mums.sd.rec1394.225

Health conditions studied

1

Description of health condition studied
resorbed mandible alveolar bone in edentulous patient

ICD-10 code

K06.9

ICD-10 code description
Disorder of gingiva and edentulous alveolar ridge, unspecified

Primary outcomes

1

Description
Cell Migration

Timepoint
3 and 7 days following end of treatment

Method of measurement
Flow cytometry

2

Description
Vestibule depth

Timepoint
pre treatment, 1 week, 2 weeks, 4 weeks, and 3 months following end of treatment

Method of measurement
with calliper with graduation of 0.1 millimetres

Secondary outcomes

1

Description
Pain

Timepoint
1 week following the end of treatment

Method of measurement
Oral questionnaire

2

Description
Local infection

Timepoint
1 week following the end of treatment

Method of measurement
Clinical assessment

Intervention groups

1

Description
use of amniotic membrane as graft material for covering denuded periosteum after vestibuloplasty using Clark's technique

Category
Treatment - Surgery

2

Description
use of acellular dermal matrix as graft material for covering denuded periosteum after vestibuloplasty using

Clark's technique
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry Faculty- Dental and Oral prosthodontics
Department
Full name of responsible person
Danial Babaki
Street address
Azadi square
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Deputy of Mashhad University of Medical
Science
Full name of responsible person
Mahdi Gholami
Street address
Daneshgah Street-
City
Mashhad
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Research Deputy of Mashhad University of Medical
Science
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
Dentistry Faculty- Mashhad university of medical
science
Full name of responsible person
Danial Babaki
Position

Dentistry Student and M.Sc student of cell and
molecular biology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Dentistry Faculty- Mashhad University of Medical
Science

Full name of responsible person

Mahdi Gholami

Position

Oral and Maxillofacial Surgeon/ Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Dentistry Faculty- Mashhad University of Medical
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Full name of responsible person

Danial Babaki

Position

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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