Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Evaluation of the effect of platelet rich fibrin and acellular dermal matrix on soft tissue thickness in patients receiving dental implants

Protocol summary

Study aim
Comparison of the effect of platelet rich fibrin and acellular dermal matrix on soft tissue thickness in patients receiving dental implants

Design
Two arm parallel group randomized trial with blinded outcome assessment and data analysis

Settings and conduct
The study will be run in Dentistry faculty of Mashhad University of Medical Sciences. After receiving informed consent, a blind calibrated examiner will measure the tissue thickness. Measurements will be repeated after 3 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patient who need dental implants in posterior mandible with thin gingival biotype. Exclusion criteria: any medical contraindication for dental implants; need for soft tissue or hard tissue augmentation.

Intervention groups
Platelet rich fibrin and acellular dermal matrix will be used for soft tissue thickening in intervention and control group, respectively.

Main outcome variables
Soft tissue thickness in the area of implant placement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200914048713N1**
Registration date: **2021-11-30, 1400/09/09**
Registration timing: **prospective**

Last update: **2021-11-30, 1400/09/09**
Update count: **0**

Registration date
2021-11-30, 1400/09/09

Registrant information

Name
moein khojaste

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-05, 1400/10/15

Expected recruitment end date
2022-06-05, 1401/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Evaluation of the effect of platelet rich fibrin and acellular dermal matrix on soft tissue thickness in patients receiving dental implants

Public title
Effect of platelet rich fibrin on soft tissue thickness

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient who need dental implants in posterior mandible

Less than 2 mm soft tissue thickness Adequate width and height of the bone healthy soft tissue Lack of previous hard tissue augmentation Lack of previous soft tissue augmentation

Exclusion criteria:

Age less than 18 and more than 60 years old Medical contraindication for dental implants Untreated periodontitis Uncontrolled diabetes mellitus Smokers and alcoholic patients

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be done using "randomization.com" website. All data will be placed in opaque sealed envelop and will be opened by nurse before surgery.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person who measures soft tissue thickness at baseline and follow up is totally blind to the type of intervention. Person who analyzes the data is also blind. blinding of the patients and the surgeon is not possible.

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

Vakil abad street, vest door of ferdowsi university, faculty of dentistry

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2021-08-04, 1400/05/13

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1400.081

Health conditions studied

1

Description of health condition studied

Thin soft tissue

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Soft tissue thickness

Timepoint

Baseline, 3 months postoperative

Method of measurement

Endodontic reamer, gauge with 0.1 mm accuracy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 3 layers of platelet rich fibrin will be placed under soft tissue before suturing.

Category

Treatment - Other

2

Description

Control group: An acellular dermis membrane with 0.6-1 mm thickness will be placed under patients soft tissue before suturing.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Dental School

Full name of responsible person

Amir Moeen Taghavi

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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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
Necessary information will be sent to the journal that publishes the article.
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