

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of sulcular incision versus papilla sparing incision on the tooth-implant papilla dimensions, a randomized clinical study

Protocol summary

Study aim

Determining clinical indices comparing two types of sulcular incision and papilla sparing incision for implant placement

Design

Clinical trial with a control group, with parallel groups, triple-blind, randomized, phase 3 on 46 patients, for randomization, sealed envelope method and random number table are used.

Settings and conduct

Place: Faculty of Dentistry, Tehran University of Medical Sciences, intervention: papilla sparing incision, control: sulcular incision, blinding: triple-blind (researcher, statistical analyzer and participants)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1- Patients over 18 years of age who refer to the periodontics department of Tehran Faculty of Dentistry need implant placement in the edentulous area in the anterior or posterior region in a delayed or late implantation. 2- The presence of teeth on the mesial or distal side or both sides of the edentulous area 3- Non-smokers or people who consume less than 10 cigarettes per day 4- Having informed consent Exclusion Criteria: 1- Pregnancy and lactation and suffering from diabetes 2- The need for an implant in the second molar area towards the back 3- The tooth adjacent to the edentulous area has a clinical attachment loss of more than 2 mm 4- The need for simultaneous soft and hard tissue reconstruction and flap advancement at the time of implant placement 5- Implant adjacent to the free end edentulous area 6- Patient's lack of consent to continue cooperation in the research plan

Intervention groups

Intervention: In this group, a papilla sparing incision is made in the desired area for implant placement. Control: In this group, a sulcular incision is made in the desired area for the implant.

Main outcome variables

Changes in the height and volume of the papilla adjacent

to the edentulous area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231115060069N1**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Mahsa Etemadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4279 4500

Email address

m-etemadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-24, 1403/01/05

Expected recruitment end date

2024-08-20, 1403/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	sealed envelope, then on the day of the surgery, one of the envelopes is opened and the surgery is performed based on that.
Scientific title	Blinding (investigator's opinion)
Evaluation of the effect of sulcular incision versus papilla sparing incision on the tooth-implant papilla dimensions, a randomized clinical study	Triple blinded
Public title	Blinding description
Evaluation of the effect of two incision techniques on the soft tissue dimensions around the implant	patients participating in the study knowing that they are participating in a research study, are blinded to the allocation to the desired treatment group, the researcher and the statistical analyst are blinded to the type of surgical technique performed in each patient.
Purpose	Placebo
Treatment	Not used
Inclusion/Exclusion criteria	Assignment
Inclusion criteria:	Parallel
patients aging over 18 years who refer to the periodontics department of Tehran Faculty of Dentistry need implant placement in the edentulous area in anterior or posterior region in a delayed or late implantation. The presence of teeth on the mesial or distal side or both sides of the edentulous area patients without systemic conditions interfering with surgery (ASA 1 or 2) Non-smokers or less than 10 cigarettes per day presence of periodontal health (less than 4 areas with probe depth greater than 4 mm) Fullmouth bleeding score and fullmouth plaque score less than 25% Having informed consent	Other design features
Exclusion criteria:	
Pregnancy and lactation Having diabetes The need for an implant in the posterior second molar region The tooth adjacent to the edentulous area have a clinical attachment loss of more than 2 mm The need for simultaneous soft and hard tissue reconstruction and flap advancement at the time of implant placement The implant adjacent to the free end edentulous area The patient's lack of consent to continue cooperation in the research project Severe side effects during treatment The impossibility of placing the healing abutment on the day of surgery Improper position of the implant	Secondary Ids
Age	empty
From 18 years old	Ethics committees
Gender	<u>1</u>
Both	Ethics committee
Phase	Name of ethics committee
3	Ethics committee of Tehran University of Medical Sciences
Groups that have been masked	Street address
- Participant - Investigator - Outcome assessor - Data analyser	North Karegar St, Faculty of Dentistry, Tehran University of Medical Sciences, Tehran-Iran
Sample size	City
Target sample size: 46	Tehran
Randomization (investigator's opinion)	Province
Randomized	Tehran
Randomization description	Postal code
Simple and individual randomization; People who meet the entry criteria are assigned a number and enter the study. Then the patients are randomly divided into 2 intervention and control groups by the table of random numbers. For allocation concealment, the coded sealed envelope method with the random sequence will be used. The name of the surgical method is written inside a	Approval date
	2023-11-15, 1402/08/24
	Ethics committee reference number
	R.TUMS.DENTISTRY.REC.1402.080
	Health conditions studied
	<u>1</u>
	Description of health condition studied
	Incision technique in implant insertion
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	<u>1</u>
	Description
	Changes in the height of the papilla adjacent to the edentulous area
	Timepoint
	Baseline, 3 months after surgery
	Method of measurement
	image j software

2

Description

Changes in the volume of the papilla adjacent to the edentulous area

Timepoint

Baseline, 3 months after surgery

Method of measurement

image j software

Secondary outcomes

1

Description

The presence of scar tissue

Timepoint

3 months after surgery

Method of measurement

mucoal scarring index

2

Description

Implant position

Timepoint

Immediately after implant placement

Method of measurement

Parallel periapical radiograph

3

Description

The amount of gingival recession

Timepoint

At baseline, 3 months after surgery

Method of measurement

Michigan probe with Williams numbering as the difference in the distance of the gingival margin from the mucogingival line

4

Description

Probing depth

Timepoint

The baseline, 3 months after surgery

Method of measurement

Michigan probe with Williams numbering in buccal, lingual, mesial and distal points of adjacent teeth

Intervention groups

1

Description

Intervention group: papilla sparing incision

Category

Treatment - Surgery

2

Description

Control group: sulcular incision

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Mahsa Etemadi

Street address

North Karegar St, Faculty of Dentistry, Tehran University of Medical Sciences, Tehran-Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

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
Mahsa Etemadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available