

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of hyaluronic acid gel on the stability of dental implants

Protocol summary

Study aim

Investigating the effect of hyaluronic acid gel on the stability of dental implants

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2 on 16 patients using coin toss method for randomization.

Settings and conduct

This study is a split-mouth randomized clinical trial on patients with two posterior edentulous areas who referred to the periodontics department of Tehran Azad University of Medical Sciences for implant treatment will be done.

Participants/Inclusion and exclusion criteria

Inclusion: Patients over 18 years of age, patients with an O'LEARY Index (plaque control index) less than 20%, with two posterior edentulous areas in the upper or lower jaw, no need for BONE AUGMENTATION and no fenestration. Sensation, absence of pain, swelling and infection in the surgical area. exclusion: systemic disease, malignancy, cervical radiotherapy, autoimmune, pregnancy, need for GBR, cThe need to submerge in implant placement, smoking, alcohol consumption, steroid use and drugs affecting periodontal tissues and bisphosphonates.

Intervention groups

The number of 16 patients who are candidates for implant treatment, who have two posterior edentulous areas in the upper or lower jaw without the need for bone, without fenestration and synthesis and bone infection, are selected. After preparing the osteotomy cavity according to the company's drilling sequence, the implants are placed in the cavities so that one of the cavities is randomly impregnated with 0.4 ml of hyaluronic acid gel (case group) and the other cavity remains unchanged (control group).

Main outcome variables

Implant stability (based on ISQ changes)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040460N9**

Registration date: **2022-09-06, 1401/06/15**

Registration timing: **prospective**

Last update: **2022-09-06, 1401/06/15**

Update count: **0**

Registration date

2022-09-06, 1401/06/15

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2024-11-05, 1403/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of hyaluronic acid gel on the stability of dental implants	
Public title	Investigating the effect of hyaluronic acid gel
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients over 18 years of age Patients with O'LEARY Index (plaque control index) less than 20% Having two posterior edentulous areas in the upper or lower jaw (teeth 4 to 7) No need for BONE AUGMENTATION and no fenestration and desensation No need for BONE AUGMENTATION and no fenestration and desensation Exclusion criteria: Systemic disease such as uncontrolled diabetes, malignancy, head and neck radiotherapy, autoimmune disease that makes soft and hard tissue repair difficult Pregnancy Need GBR The implant cannot be placed in one step and it needs to be submerged Presence of pain, swelling and infection in the surgical area Smoking Alcohol consumption Use of steroids and drugs affecting periodontal tissues and bisphosphonates
Age	From 18 years old
Gender	Both
Phase	2
Groups that have been masked	Care provider
Sample size	Target sample size: 16
Randomization (investigator's opinion)	Randomized
Randomization description	The samples will be selected from among the patients who have two posterior edentulous areas (teeth 4 to 7) in the upper or lower jaw with specific entry and exit criteria who are candidates for receiving implants in these areas. The sampling method is based on the target and continues until the desired number is reached, and then randomization is done using a coin in each person to allocate two areas to the test and control groups.
Blinding (investigator's opinion)	Single blinded
Blinding description	The placement of the implant and the times determined by an examiner who was completely blinded to the surgical procedure are performed.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethics Committee of Tehran Islamic Azad University of Medical Sciences
Street address	No. 9, Nistan 9th, Pasdaran St.
City	Tehran
Province	Tehran
Postal code	1946853314
Approval date	2022-04-30, 1401/02/10
Ethics committee reference number	IR.IAU.DENTAL.REC.1401.019
Health conditions studied	
1	
Description of health condition studied	Investigating the effect of hyaluronic acid gel on the stability of dental implants
ICD-10 code	K02.52
ICD-10 code description	Dental caries on pit and fissure surface penetrating into dentin
Primary outcomes	
1	
Description	Implant stability (based on ISQ changes)
Timepoint	Before the intervention and after 2, 4 and 8 weeks after placing the fixture
Method of measurement	Penguin RFA device
2	
Description	Hyaluronic acid
Timepoint	Before starting the intervention
Method of measurement	Observation
Secondary outcomes	
1	
Description	Implant stability (based on ISQ changes)

Timepoint

Before the intervention and after 2, 4 and 8 weeks after placing the fixture

Method of measurement

Penguin RFA device

Intervention groups

1

Description

Intervention group: 16 patients who are candidates for implant treatment, who have two posterior edentulous areas in the upper or lower jaw without the need for bone, without fenestration and synthesis and bone infection, are selected. In the intervention group, after preparing the osteotomy cavity according to the company's drilling sequence, the implants are randomly placed in one of the cavities with 0.4 ml of hyaluronic acid gel.

Category

Treatment - Surgery

2

Description

Control group: 16 patients who are candidates for implant treatment, who have two posterior edentulous areas in the upper or lower jaw, without the need for bone, without fenestration and synthesis and bone infection, are selected. In the control group, after preparing the osteotomy cavity according to the drilling sequence of the company, the implants are placed in the cavities without any changes.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Azad University of Medical Sciences, Tehran

Full name of responsible person

Farzaneh Orei

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No. 9, Nistan 9th, Pasdaran St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Arash Azizi

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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

Islamic Azad University

Full name of responsible person

Nima Nadafpour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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