Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Inclsion: 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
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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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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
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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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