Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Survey of implant stability changes (ISQ or Implant Stability Quotient) in SLA implants with and without calcium solution

Protocol summary

Study aim

Comparison of implant stability changes (ISQ or Implant Stability Quotient,) in SLA and Impregnated with Ca solution in patients referred to the implant department of Dentistry Azad University and a private clinic

Design

A randomized clinical trial study to examine if there is a difference in the integration of an implant in two different surfaces of acid etching-sandblasting and calcium-impregnated .Clinical evaluation of implants over time will be done using the ISQ (Implant Stability Quotient,) by the Osstell system.

Settings and conduct

The osteotomy cavity would be performed. And if there is an initial Insertion Torque of above 25N samples, then after the ISQ assessment, the initial stability will be recorded,By closing the Gingival former, the implants will be placed in a single step. 4 weeks and 8 weeks after surgery, Gingival former are reopened and an RFA and ISQ record will be assessed. During this time, implants will be examined for clinical conditions n.

Participants/Inclusion and exclusion criteria

30 patients without at least 2 posterior teeth in the mandible or maxillary. Entry criteria for the study: 1- At least two implants in the posterior maxilla and mandible in each patient 2. Agree with the terms of the research and consent letter Output criteria of the study: 1. Failure to reach the initial torque above 25N 2- Bone Dehisense Existence 3. Bone typing D4 (decision by surgeon) 4. The presence of uncontrolled systemic disease 5- Top 10 cigarettes per day 6. History of the use of bisphosphonates 7.Need for bone graft

Intervention groups

The control group of implants with SLA level (Osstem SA surface, TS||| SA South Korea) and impregnated with Ca solution group (osstem CA surface, TS||| CA South Korea)

Main outcome variables

Implant stability (ISQ) in case and control group immediately after surgery, 4 weeks and 8 weeks after surgery

General information

Reason for update

Acronym

SLA, ISQ

IRCT registration information

IRCT registration number: **IRCT20180714040460N5**
Registration date: **2019-07-03, 1398/04/12**
Registration timing: **prospective**

Last update: **2019-07-03, 1398/04/12**
Update count: **0**

Registration date

2019-07-03, 1398/04/12

Registrant information

Name

Nima Nadafpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-11, 1398/04/20

Expected recruitment end date

2019-11-01, 1398/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Survey of implant stability changes (ISQ or Implant Stability Quotient) in SLA implants with and without calcium solution

Public title
Comparison of Impact of Implant with Two SLA Levels and Calcium Impregnated on Bone around the Implant

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least two implants in the posterior of maxilla and mandible in each patient Agreement with research conditions and Signature of consent

Exclusion criteria:
Failure to achieve primary torque above 25N Bone dehiscence existence Bone D4 Type (Decision by Surgeon) Over 10 cigarettes a day History of taking bisphosphonates not required to bone graft The presence of an uncontrolled systemic related disease

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
30 patients without at least 2 posterior teeth in Mandible maxilla were randomly divided into two groups: control and test group

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method By using a coin flipping, we assign one of two implant sites to the SLA, and the other to a impregnated calcium implant.

Blinding (investigator's opinion)
Double blinded

Blinding description
Only the practitioner and surgeon knows the difference between the site of the two implants and the participant, evaluator, analyst and safety committee, and data monitoring are aware of the type of implants used and are blind to the position of each implant.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of central organization of Islamic Azad university

Street address
No.9 , 9th Neyestan Ave., Pasdaran Ave., Tehran

City
Tehran

Province
Tehran

Postal code
19585175

Approval date
2018-05-29, 1397/03/08

Ethics committee reference number
IR.IAU.DENTAL.REC.1397.041

Health conditions studied

1

Description of health condition studied
Implant stability changes (ISQ or implant stability factor) in SLA implants and impregnated with calcium solution

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
ISQ(Implant Stability Quotient)

Timepoint
Immediately after surgery, 4 weeks and 8 weeks after surgery

Method of measurement
Osstell Device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Implants impregnated with calcium to change superficial properties that increase bone responses and accelerate osteointrigation.

Category
Treatment - Devices

2

Description
Control group: SLA implants without calcium solution
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Implant Department of Islamic Azad University and a private clinic*
Full name of responsible person
Nima nadaf pour
Street address
No.9 , 9th Neyestan Ave., Pasdaran Ave., Tehran
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Phone
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Email
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2

Recruitment center
Name of recruitment center
private office of Dr.Nima Naddaf pour
Full name of responsible person
Nima Naddaf pour
Street address
Unit.24 , No.38 , Juy pa alley , Sarv cross , Paknejad blvd , Saadat Aabad Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Nima nadafpour
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No.9 , 9th Neyestan Ave., Pasdaran Ave., Tehran
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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
Islamic Azad University
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
Dentistry
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Person responsible for scientific inquiries

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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

There is no more information with respect to the subject

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