

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Dehiscence 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

Email address

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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

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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

Ostell Device

Secondary outcomes

empty

Intervention groups**1****Description**

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

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

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

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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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