

# 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 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

n\_nadaf@dentaliau.ac.ir

##### 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**

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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

##### Phone

+98 21 2256 4571

##### Email

n\_nadaf@dentaliau.ac.ir

### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1998798331

##### Phone

+98 21 2676 7768

##### Email

n\_nadaf@dentaliau.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Nima nadafpour

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

19585175

##### Phone

+98 21 2256 4571

##### Email

n\_nadaf@dentaliau.ac.ir

#### 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

##### Street address

Unit.24 ,No.38 ,Juy pa alley , Sarv cross ,Paknejad blvd ,Saadat Aabad Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1998798331

##### Phone

+98 21 2676 7768

##### Fax

##### Email

n\_nadaf@dentaliau.ac.ir

## Person responsible for scientific 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

**Street address**

Unit.24 ,No.38 ,Juy pa alley , Sarv cross ,Paknejad blvd ,Saadat Aabad Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1998798331

**Phone**

+98 21 2676 7768

**Fax**

**Email**

n\_nadaf@dentaliau.ac.ir

**Person responsible for updating data**

**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

**Street address**

Unit.24 ,No.38 ,Juy pa alley , Sarv cross ,Paknejad blvd ,Saadat Aabad Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1998798331

**Phone**

+98 21 2676 7768

**Fax**

**Email**

n\_nadaf@dentaliau.ac.ir

**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