

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Comparison of Immediate and Delayed Implantation on Insertion Torque and Primary Stability

Protocol summary

Study aim

Comparison of Immediate and Delayed Implantation on Insertion Torque and Primary Stability

Design

Clinical trial, with control group, double blinded, split mouth, on 8 patients

Settings and conduct

The clinical trial study would be done in Islamic azad university dental branch in 2019-2020. Implants with SLA surface in immediate method (case group) and delayed method (control group) will be inserted while they are similar in length, diameter and their position in jaw.

Participants/Inclusion and exclusion criteria

Implants with SLA surface in same length diameter and place in jaw will be inserted in delayed(control) or immediate (case) approach. These patient will be removed:heavy smokers, uncontrolled diabete, poor oral hygiene, pregnant, need ridge augmentation, long term use of NASIDs, oral or intravenous bisphosphonat usage, untreatment periodontal disease

Intervention groups

Recently extracted area will received immediate implant and will be a case group and area in same or opposite sextant will receive delayed implant and will be control group.

Main outcome variables

Primary stability and insertion torque of immediate implantation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048522N1**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Ali Hassani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-02, 1398/07/10

Expected recruitment end date

2020-10-11, 1399/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Immediate and Delayed Implantation on Insertion Torque and Primary Stability

Public title

Comparison of immediate and delayed implantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy systemic conditions Have at least one hopeless

tooth to extract An edentulous area with similar position in jaw and bone density to area with hopeless tooth

Exclusion criteria:
 Heavy smoker Uncontrolled diabetes Ridge augmentation necessity Long term use of NASIDs Lack of space from opposite jaw that cannot use implant Oral or intravenous use of Bisphosphonate Untreatment periodontal disease Malocclusion Severe cavities Periapical lesions Unacceptable occlusion because of over eruption or tilt of teeth to edentulous area

Age
 No age limit

Gender
 Both

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **8**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Control area will be implanted in delayed approach and case area will be implanted in immediate approach that have hopeless teeth to extract

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Iran national committee for ethics in biomedical research

Street address
 NO.58, Jafary alley, Afshary Ave., Pasadaran, Tehran, Iran

City
 Tehran

Province
 Tehran

Postal code
 1666833138N

Approval date
 2019-06-23, 1398/04/02

Ethics committee reference number
 IR.IAU.DENTAL.REC.1398.023

Health conditions studied

1

Description of health condition studied

Treatment of edentulous with implant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measure of primary stability of immediate implantation

Timepoint

Immediately after insertion of implant

Method of measurement

Using Osstell and numbered torque wrench

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The site to receive the implant immediately. After the atraumatic extraction of the tooth and then the full thickness flaps will be prepared under local anesthesia and the osteotomy areas will be prepared according to the manufacturer's instructions. Exploratory examination of the socket after extraction will be performed by the probe to identify defects - especially in the buccal wall - which in this study are considered immediate contraindications. According to the existing protocol for one-step surgery, two implants will be placed in each patient by a calibrated torque wrench for implant placement and torque measurement. The amount of torque for each implant is measured relative to time and the maximum final value will be calculated in Ncm. Immediately after implant placement, an RF analyzer will be used to directly measure initial stability. The resulting data will be displayed as a graph with RF-domain axes. The RF values calculated from the amplitude peak will be displayed as a quantitative scale from zero to 2 called the Implant stability quotient (ISQ). Thus, the higher the ISQ, the higher the stability of the implant. After surgery, the ISQ value for each implant will be measured by the same surgeon (initial stability). The flaps are returned to their original position by the sling suture. All implant stability measurements are repeated three times for each case and the average of three numbers will be recorded as the final value. If the difference between these three numbers in an implant is more than one unit, or indicates an error device, the measuring device will be disconnected, reconnected and the measurement will be performed again.

Category

Treatment - Surgery

2

Description

Control group: On the edentulous side, full-thickness flaps will then be provided under local anesthesia, and osteotomy areas will be prepared according to the manufacturer's instructions. A scale will be placed for implant placement and torque measurement. The amount of torque for each implant is measured relative to time and the maximum final value will be calculated in Ncm. Immediately after implant placement, an RF analyzer will be used to directly measure initial stability. The resulting data will be displayed as a graph with RF-domain axes. The RF values calculated from the amplitude peak will be displayed as a quantitative scale from zero to 2 called the Implant stability quotient (ISQ). Thus, the higher the ISQ, the higher the stability of the implant. After surgery, the ISQ value for each implant will be measured by the same surgeon (initial stability). The flaps are returned to their original position by the sling suture. All implant stability measurements are repeated three times for each case and the average of three numbers will be recorded as the final value. If the difference between these three numbers in an implant is more than one unit, or indicates an error device, the measuring device will be disconnected, reconnected and the measurement will be performed again.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Implant Research Center of Islamic Azad University of Dentistry, Tehran

Full name of responsible person

Sahar Seifollahi

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NO.58, Jafary alley, Afshary Ave., Pasadaran, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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9th NeyestanAve., Pasdaran Ave,

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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

Sahar Seifollahi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

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Latest degree

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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