Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 Lake of space from opposite jaw that cannot use implant Oral or intravenous use of Bisphosphonate Untreatment periodental 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 ti 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 committe for ethics in biomedical research

Street address

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

City

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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

Immediatly 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 atroumatic 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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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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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