Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the primary stability of the DRI (Dr Rokn Implant) Iranian implant system in fresh socket implantation with the Osstell Mentor device

Protocol summary

Study aim
Evaluation of the primary stability of the DRI Iranian implant system in fresh socket implantation with the Ostell Mentor device

Design
Clinical trial without control group, with an intervention group, who are candidates to receive implants. The sample size is 26, which increases to 30 considering the loss of samples, and data analysis is done with PASS software.

Settings and conduct
There is only one intervention group in which patients receive dental implants. In Dentistry faculty of Mashhad university of medical science, without blinding, after atraumatic extraction of hopeless tooth, length and width of the alveolar bone is measured and then DRI implant is inserted and healing abutment is placed and screwed to the implant.

Participants/Inclusion and exclusion criteria
inclusion criteria: patients 18 to 45 years old with anterior or posterior, upper or lower, hopeless tooth which is a candidate of fresh socket implantation. exclusion criteria: 1-need for ridge augmentation 2-infection in dental socket 3-smoker patient 4-uncontrolled diabetes or other disease affecting implantation 5-on a bisphosphonate therapy 6-active periodontal disease 7- heavy bruxism and clenching 8-patient not willing to be followed up 9-pregnancy

Intervention groups
After atraumatic extraction of hopeless tooth, length and width of the alveolar bone is measured and then DRI implant (made in Iran and its main component is grade 5 titanium) is inserted and healing abutment is placed and screwed to the implant.

Main outcome variables
ISQ(Implant Stability Quotient) number reported by the Osstell Mentor device

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241023063477N1**
Registration date: **2025-01-03, 1403/10/14**
Registration timing: **retrospective**

Last update: **2025-01-03, 1403/10/14**
Update count: **0**

Registration date
2025-01-03, 1403/10/14

Registrant information

Name
Alireza Raf'ati Gonabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3867 0054

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rafatia982@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-10-28, 1403/08/07

Expected recruitment end date
2024-11-27, 1403/09/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the primary stability of the DRI (Dr Rokn Implant) Iranian implant system in fresh socket implantation with the Osstell Mentor device

Public title
Evaluation of the primary stability of the DRI Iranian implant system

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 18 to 45 years with anterior or posterior, upper or lower, hopeless tooth, which is candidate for fresh socket implantation

Exclusion criteria:
Need for ridge augmentation infection in dental socket smoker patient uncontrolled diabetes or other disease affecting implantation on a bisphosphonate therapy active periodontal disease heavy bruxism and clenching patient not willing to be followed up pregnancy

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

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
Ethics committee of Dentistry faculty of Mashhad University of Medical Sciences

Street address
Ethics committee, Research Deputy, Dentistry faculty of Mashhad University of medical sciences, Vakil Abad Blvd

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948559

Approval date
2024-10-19, 1403/07/28

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1403.125

Health conditions studied

1

Description of health condition studied
Dental caries candidate of implantation

ICD-10 code
K02

ICD-10 code description
Dental caries

Primary outcomes

1

Description
ISQ (Implant Stability Quotient) number reported by Osstell Mentor Device of implant stability in alveolar bone

Timepoint
3 to 4 months after intervention (implantation)

Method of measurement
with the Osstell Mentor Device

Secondary outcomes

empty

Intervention groups

1

Description
DRI dental implant is made in Iran and its main component is grade 5 titanium. DRI implant has Iran Ministry of Health certificates with license number of 46455052 verified at 2022-06-29 and ISO13485 standard, produced by Negin Kasht Dandan company, with national ID of 14003495210. After extraction surgery of hopeless decayed tooth, dental implant fixture is implanted via fresh socket method, then Chlorhexidine 0.2% mouth rinse Bid, Ibuprofen 400mgTID, and Amoxicillin 500mg TID is prescribed. 3 to 4 months after implantation, Evaluation of implant stability is measured with Osstell Mentor device.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry Faculty of Mashhad university of Medical sciences
Full name of responsible person
Mahdi Gholami
Street address
Dentistry Faculty of Mashhad university of Medical sciences, Vakil Abad Boulevard
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Email
j.m.dental.s@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Research and Technology Vice-Chancellor, Qurashi Building, Daneshgah St
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Postal code
9138813944
Phone
+98 51 3841 1538
Email
vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
Mashhad University of Medical Sciences
Full name of responsible person
Mahdi Gholami
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact
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Mahdi Gholami

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
X-ray radiographs of patients with age, gender and teeth without revealing their identity, plus the reported numbers of the Stell Mentor device
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers in the field of medical sciences
Under which criteria data/document could be used
For use in meta analysis
From where data/document is obtainable
gholamimh@mums.ac.ir
What processes are involved for a request to access data/document
Give an e-mail mentioning personal details and organizational affiliation
Comments