Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of clinical and serological responses after post full mouth implantation in single visit versus multiple visits

Protocol summary

Study aim
Evaluation of clinical and serological responses after post full mouth implantation in single visit versus multiple visits

Design
A clinical trial with a parallel intervention group, single-blind, randomized, on 60 patients. The sampling method is random. Randomization using a table of random numbers is the Random Allocation Software.

Settings and conduct
Patients referred to the Faculty of Dentistry in Tabriz, who are candidates for full oral implants, will participate in the study. Patients are randomly assigned to one of the groups. The same surgeon will treat patients of both groups. Flap and drilling protocol and placement will be done as standard. In the intervention group, the patient will receive the complete implant in one session, and in the control group, in two or three sessions. One day before implant placement and 2 and 7 days after surgery, serum inflammatory biomarkers, WBC, and CRP will be measured. 24 hours after the operation, 48 hours, and seven days after implant placement, the pain level will be measured by a ten-point Visual Analogue Scale (VAS). The rate of wound healing in the two groups will be compared. The evaluating researcher will not know about the type of intervention performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Plaque and bleeding index less than 20%, sufficient keratinized bone and gum, suitable jaw anatomy for implant placement, requiring at least 12 to 14 implant units. Exclusion criteria: Untreated periodontal diseases and bone cysts, bisphosphonate therapy

Intervention groups
Intervention: Patients receiving implants in one session. Control: patients receiving implants in two or three sessions.

Main outcome variables
Inflammatory biomarkers, serum WBC and CRP levels. Pain intensity. Wound healing rate.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221110056464N1**
Registration date: **2023-01-15, 1401/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-15, 1401/10/25**
Update count: **0**

Registration date
2023-01-15, 1401/10/25

Registrant information

Name
Ahmad Afrashteh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-31, 1401/10/10

Expected recruitment end date
2023-01-20, 1401/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of clinical and serological responses after post full mouth implantation in single visit versus multiple visits

Public title
The difference in full mouth implant placement in one session and multiple visits

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who need a full mouth implant Healthy gum condition

Exclusion criteria:
Pregnant and lactating women Having any systemic diseases such as diabetes Patients receiving antibiotics in the last six months Patients receiving corticosteroid drugs Use of non-steroidal anti-inflammatory drugs for osteoarthritis rheumatism Addiction to drugs, smoking or alcohol History of head and neck radiotherapy

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling will be done among the patients referred to the Faculty of Dentistry in Tabriz who are eligible for the study. The randomization method is simple, and its unit is individual. Our tool for randomizing a table of random numbers. Based on this, the type of treatment is marked with codes A (intervention) and B (control) and placed inside the sealed envelopes. The envelopes are placed in a bag and mixed. Then it is randomly selected from the bag, and treatment is given to the patient by observing the code.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single-blind, both the patient and the attending physician will know the type of treatment. The evaluating researcher will not know about the type of intervention performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
3rd Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht St.Tabriz.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2022-10-31, 1401/08/09

Ethics committee reference number
IR.TBZMED.REC.1401.713

Health conditions studied

1

Description of health condition studied
Dental Implant

ICD-10 code
Z96.5

ICD-10 code description
Presence of tooth-root and mandibular implants

Primary outcomes

1

Description
Serum CRP and WBC levels

Timepoint
One day before implant placement and 48 hours after surgery and 7 days after surgery

Method of measurement
It will be done through blood tests of patients.

2

Description
The amount of pain

Timepoint
48 hours after surgery and 7 days after surgery

Method of measurement
Visual Analogue Scale

3

Description
Wound healing rate

Timepoint
One week after surgery
Method of measurement
EHS (EARLY WOUND HEALING) evaluation will be done through three indicators: 1. Clinical signs of re-epithelialization (CSR) (score 0: visible distance between cut edges, score 3: contact between cut edges, score 6: Sticky cutting edges) 2. Clinical signs of hemostasis (CSH) (score 0: bleeding at the cut edge, score 1: the presence of fibrin at the cut edge, score 2: absence of fibrin at the cut edge) 3. Clinical signs of inflammation (CSI) (score 0: redness in More than 50% of the cut length and/or clear swelling, score 1: redness in less than 50% of the cut length, score 2: absence of redness during the cut). The sum of the scores of these three parameters will form the EHS score. Therefore, the EHS score for the ideal wound healing will be ten points, and a score of zero will indicate the worst EHS condition. The wound will be ten points. And a score of zero will indicate the worst EHS condition.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Surgery and implant placement will be done in one session. The flap and the drilling protocol and placement will be done as standard and the healing abutment will be closed as much as possible. The type of implants used will be the same for all people, and the Korean implant of Deo Company is used. All implants will be surgically implanted in the patient's mouth following the principles of infection control and based on the manufacturer's instructions. One day before implant placement and 2 and 7 days after surgery, inflammatory biomarkers, serum WBC and CRP will be measured by blood tests in the medical diagnosis laboratory. 24 hours after the operation, 48 hours, and 7 days after implant placement, the pain level will be measured by a ten-point Visual Analogue Scale (VAS). The rate of wound healing will be evaluated according to the method mentioned in measuring outcomes through three indices of clinical signs of re-epithelialization (CSR), clinical signs of homeostasis (CSH), and clinical signs of inflammation (CSI).
Category
Treatment - Other

2

Description
Control group: Surgery and implant placement will be done in two or three sessions. The flap and the drilling and placement protocol will be done as standard and the healing abutment will be closed as much as possible. The type of implants used will be the same in all people, and the Korean implant of Deo Company is used. All implants will be surgically implanted in the patient's mouth following the principles of infection control and based on the manufacturer's instructions. One day before implant placement and 2 and 7 days after surgery, inflammatory biomarkers, serum WBC and CRP will be measured by blood tests in the medical diagnosis laboratory. 24 hours after the operation, 48 hours and 7 days after implant placement, the pain level will be measured by a ten-point Visual Analogue Scale (VAS). The rate of wound healing will be evaluated according to the method mentioned in measuring outcomes through three indices of clinical signs of re-epithelialization (CSR), clinical signs of homeostasis (CSH) and clinical signs of inflammation (CSI).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry, Tabriz
Full name of responsible person
Atabak Kashefi Mehr
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Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht St., Tabriz.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Atabak Kashefi Mehr

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

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Atabak Kashefi Mehr

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

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Atabak Kashefi Mehr

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable