

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of pain intensity and amount of edema in patients treated with immediate and conventional implants

Protocol summary

Study aim

Determining and comparing the intensity of pain and the amount of edema in implants placed by the immediate and conventional method

Design

Clinical trial, single-blind, randomization with random permutations, with parallel groups

Settings and conduct

This research will be performed in Tabriz University of Medical Sciences, Faculty of Dentistry, in the academic year of 1400-1401. After implant placement, information about post-operative pain will be taken from each patient by VAS (visual analog scale) after 24 hours and 48 hours. Also to evaluate edema after 7 days the tape measure will be used. For measuring edema a line will be drawn between the corner of the lip and the tragus, and another line will be drawn from the tragus to the soft tissue pogonion ('pog'). The average of these distances before the start of surgery and 7 days it will be measured and the results will be reported.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age are admitted who either have a suitable tooth for extraction and immediate implant placement, or have an empty space in the front of the jaw for implant placement in the usual way. Exclusion criteria: moderate to severe periodontitis and diseases related to oral mucosa and connective tissue

Intervention groups

In this study, the patients will be divided into the conventional implant placement and the immediate implant placement. In the conventional implant group, the tooth is extracted first and after the extraction site is repaired, the implant is placed, but in the immediate group, which is the same as the intervention group, immediately after the tooth extraction, the implant is placed, and then pain and edema will be measured in them.

Main outcome variables

It is hoped that patients will be informed about the results of this study and the intensity of pain and the amount of edema before surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054883N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Farzam Fazli Bavi Olyae

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3551 4106

Email address

pourlak.t@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of pain intensity and amount of edema in patients treated with immediate and conventional implants

Public title
Evaluation of pain intensity and amount of edema in patients treated with immediate and conventional implants

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 18 years of age and older The tooth is suitable for extraction and immediate implant placement free space in the jaw for conventional implant placement
Exclusion criteria:
 Moderate to severe periodontitis Disease of the oral mucosa and connective tissue

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be distributed to the studied groups by using permuted block technique, in such a way that equal number of participants will enter the group of immediate implants and normal implants in consecutive but equal time intervals. The number of people is equal to the number of 10 people. They will be present in each group, in the first group, the tooth will be extracted and implant will be placed after the restoration of the extraction site, and in the second group, the implant will be placed immediately after extraction.

Blinding (investigator's opinion)
Not blinded

Blinding description

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
 Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
 Tabriz
Province
 East Azarbaijan
Postal code
 5165665931
Approval date
 2022-04-20, 1401/01/31
Ethics committee reference number
 IR.TBZMED.REC.1401.072

Health conditions studied

1

Description of health condition studied
 Evaluation of pain intensity and amount of edema in patients treated dental implants
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Pain score in Visual Analogue Scale questionnaire
Timepoint
 24 and 48 hours after implant placement
Method of measurement
 Visual Analogue Scale

Secondary outcomes

1

Description
 Determining and comparing the amount of edema in implants with tape measure
Timepoint
 Before surgery and 7 days after surgery
Method of measurement
 Tape Measurment

Intervention groups

1

Description
 Intervention group:In the first group, first the anterior tooth is extracted and 3-4 months later the implant is placed. It will be used the day after surgery as a painkiller and anti-inflammatory

Category

Rehabilitation

2**Description**

Intervention group: In the second group, the implant is placed immediately after tooth extraction. After implant placement, all patients undergoing this operation receive ibuprofen (brand name gelofen) 400 mg every 6 hours for 5 days after surgery as Will use painkillers and reduce inflammationCommunity Verified iconOpen in Google Translate•Feedb

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

School of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Tannaz Pourlak

Street address

Ground floor, Old Building of the Faculty of Pharmacy, Main Shared Campus of the Tabriz University of Medical Sciences/ Tabriz University, Golgasht Avenue, Tabriz, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Soodabeh Kimiaei

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Ground floor, Old Building of the Faculty of Pharmacy, Main Shared Campus of the Tabriz University of Medical Sciences/ Tabriz University, Golgasht Avenue, Tabriz, Iran

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Email

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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

Farzam Fazli Bavil Olyaei

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No. 152 , 17 Shahrivar Ave.

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Fax**Email**

pourlak.t@tbzmed.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Tannaz Poorlak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Names and identities of people in the data will be unidentifiable, and only the amount of edema and pain intensity related to the type of surgery will be known.

When the data will become available and for how long

Access will start 3 months after the results are published.

To whom data/document is available

Only researchers and people working in academic and scientific centers will be allowed to access the data.

Under which criteria data/document could be used

The data are only sent for further analysis in order to check on the degree of edema and pain intensity and no other analysis is allowed on them.

From where data/document is obtainable

Please send a message to the email address pourlak.t@tbzmed.ac.ir belonging to Dr. Tanaz Pourlak.

What processes are involved for a request to access data/document

The purpose and reason of the request will be reviewed.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Farzam Fazli Babil Olyaei

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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