Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 criterias: 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 criterias: 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 Bavil Olyaee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3551 4106

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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

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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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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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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 Olyaee

Position
Student

Latest degree
Medical doctor

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