

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Clinical and histologicalevaluation of socket preservation using concentrated growth factor for implant site preparation

Protocol summary

Study aim

Clinical and histologicalevaluation of socket preservation using concentrated growth factor for implant site preparation

Design

A clinical trial with a parallel intervention group, double-blind, randomized, on 45 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 bilateral extraction and candidates for implants, will participate in the study. The socket diameter will be measured by a probe. In each patient, one of the sockets will be randomly filled using a concentrated growth factor, and the other socket will not be intervened. The patient's pain level will be measured by the ten-point Visual Analogue Scale (VAS) scale up to 7 days after the operation. The quality of the soft tissue of the surgical area will be evaluated seven days after the extraction. After two months, the silent dimensions will be measured and evaluated histologically. The patient is aware of the type of treatment but does not know which side of the jaw will be used. The evaluating researcher will not know about the type of intervention performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with bilateral extraction in maxillary anterior teeth implant candidate Exclusion criteria: teeth with acute infection or periodontal problems with bone loss

Intervention groups

Intervention: use of concentrated growth factor to prepare the implant area Control: no intervention in the implant area

Main outcome variables

Mesiodistal (MD) and vestibulo-palatal/lingual (VP/L) dimensions The amount of pain Soft tissue quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221216056831N1**

Registration date: **2022-12-28, 1401/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-28, 1401/10/07**

Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

Hanieh Asadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 914 647 8978

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-18, 1401/09/27

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

Clinical and histological evaluation of socket preservation using concentrated growth factor for implant site preparation

Public title

Using growth factor to prepare the implant area

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Implant candidate patients in the area of extracted teeth
At least 18 years old
No systemic problems

Exclusion criteria:

Smokers with more than 10 cigarettes per day
Patients with allergies to any of the substances used in this study
Patients undergoing head or neck radiation therapy or chemotherapy in the 12 months prior to surgery
Pregnant or lactating patients

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **2**

One side of the jaw is used as control and the other side is used as intervention.

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. Patients do not know the type of intervention on each jaw side.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind so the patients do not know about the type of intervention on each side of the jaw. The evaluating researcher will not know about the type of intervention performed. Patients know the type of material but do not know which side of the jaw will be used.

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

Deputy of research and technology, 3rd Floor, Central building No. 2, Tabriz University of Medical Sciences, Golgasht St., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-11-14, 1401/08/23

Ethics committee reference number

IR.TBZMED.REC.1401.732

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**

Changes in mesiodistal (MD) and vestibulo-palatal/lingual (VP/L) dimensions

Timepoint

2 months after the operation

Method of measurement

The maximum diameter of the socket is measured using the William probe and recorded in both the mesiodistal and vestibulo-lingual/palatal dimensions at the crestal level.

2**Description**

The amount of pain

Timepoint

During 7 days after the operation

Method of measurement

Visual Analogue Scale

3

Description

Soft tissue quality

Timepoint

7 days after extraction

Method of measurement

The quality of the soft tissue of the surgical area (tissue color, tissue consistency, pus secretion, bleeding) will be evaluated through a modified version of Landry, Turnbull and Howley's Healing Index (HI).

Secondary outcomes

1

Description

Histomorphological factors

Timepoint

After 2 months

Method of measurement

A sample will be taken from Saket for histological evaluation. After fixation and decalcification, the samples will be stained with hematoxylin and eosin (H&E) and histomorphological factors (percentage of remaining scaffold, bone and connective tissue) will be evaluated.

Intervention groups

1

Description

Intervention group: In order to obtain concentrated growth factor, on the day of surgery, a 9 cc venous blood sample was taken from the patients and this sample will be centrifuged (Medifuge MF200; Silfradent®Srl, S. Sofia (FC), Italy) at a speed of 2400 to 2700 rpm. After tooth extraction, using a probe, the maximum socket diameter will be measured in both mesiodistal and palatal/lingual vestibule dimensions at the crestal level. One of the sockets will be filled with CGF and to preserve the biomaterial, a membrane prepared from CGF and a horizontal figure of 8 suture will be used on the socket. The pain level of the patients up to 7 days after the operation by visual analogue scale and the quality of the soft tissue of the area. Surgery (tissue color and consistency, pus discharge, bleeding) will be evaluated 7 days after extraction, through a modified version of Landry, Turnbull and Howley's Healing Index (HI). Finally, after 2 months, the patients will return and mesiodistal dimensions and vestibule palatal/lingual socket measured again from the dental socket will be sampled for histological evaluation. After fixation and decalcification, the samples will be stained with hematoxylin and eosin (H&E) and histomorphological factors (percentage of remaining scaffold, bone and connective tissue) will be evaluated. At the same time, implants will be placed in place and Guided Bone Regeneration will be performed if needed.

Category

Treatment - Other

2

Description

Control group: After tooth extraction, maximum socket diameter will be measured using a probe in both mesiodistal and palatal/lingual vestibule dimensions at the crestal level. The control socket will be restored automatically without any intervention. The pain level of patients up to 7 days after the operation by visual analogue scale and the quality of the soft tissue of the surgical area (tissue color and consistency, pus secretion, bleeding) 7 days after the extraction, through a modified version of Landry, Turnbull and Howley's Healing Index (HI) will be evaluated. Finally, after 2 months, the patients will return and mesiodistal dimensions and vestibule palatal/lingual socket measured again from the dental socket will be sampled for histological evaluation. After fixation and decalcification, the samples will be stained with hematoxylin and eosin (H&E) and histomorphological factors (percentage of remaining scaffold, bone and connective tissue) will be evaluated. At the same time, implants will be placed in place and Guided Bone Regeneration will be performed if needed.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz

Full name of responsible person

Masoumeh Faramarzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Masoumeh Faramarzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Latest degree

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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