Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 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

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Iran (Islamic Republic of)

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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 histologicalevaluation 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
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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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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
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Person responsible for updating data

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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