Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Protocol summary

Study aim

Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Design

A clinical trial with the parallel intervention group, one-way blind, randomized, random sampling method. The randomization method is simple with a random number table. 10 patients referred to the periodontics ward who required horizontal ridge reconstruction surgery and silent protection on both sides of the ridge were selected and after surgery, on one side of the collagen membrane impregnated with ACS and on the other side only collagen membrane is used. During the first week, the amount of pain and clinical symptoms and 4 months later, histological features will be evaluated.

Settings and conduct

The study will be performed in the periodontics department of Tabriz Dental School. 10 patients require horizontal ridge reconstruction surgery and silent protection on both sides of the ridge, on one side of the collagen membrane is impregnated with ACS, and on the other side, only collagen membrane is used. Pain and clinical signs will be monitored during the first week. The evaluator is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion: The same bone needed for reconstruction on both sides Candidate patients extract teeth on both sides of the jaw, Partial edentulous patients on both sides of the jaw Exclusion: Smokers, pregnant women, systemic diseases, not taking corticosteroids

Intervention groups

The intervention group included placement of collagen membrane and bone material impregnated with ACS in the postoperative area. The control group consisted of placement of collagen membrane and bone material alone in the postoperative area.

Main outcome variables

Pain rate, inflammatory symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180630040290N6**
Registration date: **2022-01-03, 1400/10/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-03, 1400/10/13**
Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Amir Reza Babaloo

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-02, 1400/10/12

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Autologous concentrated serum on the histological and clinical characteristics of soft tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Public title
Evaluation of the effect of concentrated serum on histological and clinical characteristics of dental tissue
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The amount of bone needed for reconstruction is the same on both sides. Candidate patients extract teeth on both sides of the jaw Partial edentulous patients on both sides of the jaw
Exclusion criteria:
smokers Pregnant women
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **10**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients require horizontal ridge reconstruction surgery and Horizontal Bone Augmentation and Socket Preservation surgery
Randomization (investigator's opinion)
Randomized
Randomization description
A random sampling method is available among people referring to the periodontics department of Tabriz Dental School. The method of randomization is simple and its unit is individual. Our tool is to randomize the table of random numbers. Also, treatment was assigned to patients randomly. The type of treatment was identified by code A (intervention) and B (control) and placed inside sealed envelopes; The envelopes were then placed in a bag and shaken. Then, it was accidentally taken out of the bag, and after observing the code, the treatment was given to the patient. The evaluator was not aware of the type of treatment.
Blinding (investigator's opinion)
Single blinded
Blinding description
The present study is one-way blind and the evaluator will also be is not informed about the type of treatment.
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 office of Tabriz University of Medical Sciences, Golgasht Ave, Azadi Blvd
City
Tabriz
Province
East Azarbaijan
Postal code
5165687386
Approval date
2021-07-12, 1400/04/21
Ethics committee reference number
IR.TBZMED.REC.1400.353

Health conditions studied

1

Description of health condition studied
Horizontal alveolar bone loss
ICD-10 code
K06.3
ICD-10 code description
Horizontal alveolar bone loss

Primary outcomes

1

Description
Pain measurement
Timepoint
During a week
Method of measurement
Visual Analogue Scale

2

Description
Clinical symptoms
Timepoint
During a week
Method of measurement
REEDA (Redness, edema, ecchymosis, discharge from the wound, approximation)

Secondary outcomes

1

Description
Histological features
Timepoint
4 months later
Method of measurement
Pathology laboratory

Intervention groups

1

Description
Intervention group: Patients in need of horizontal ridge reconstruction surgery and silent protection on both sides of the ridge are selected and placed for implant placement. An ACS-impregnated collagen membrane is then applied to one side.During the first week after surgery, the clinical features of soft tissue such as pain in the area with Visual analogue scale (VAS) and other clinical symptoms such as swelling, redness, sensation of the wound, etc. are evaluated with REEDA index and report results. Becomes.Also, 4 months after surgery during implant surgery, a piece of soft tissue is punched at the implant site and sent to the laboratory to examine the histological characteristics of the soft tissue.
Category
N/A

2

Description
Control group: Patients in need of horizontal ridge reconstruction surgery and silent protection on both sides of the ridge are selected and placed for implant placement. On the opposite side, only the collagen membrane is used.During the first week after surgery, the clinical features of soft tissue such as pain in the area with Visual analogue scale (VAS) and other clinical symptoms such as swelling, redness, sensation of the wound, etc. are evaluated with REEDA index and report results. Becomes.Also, 4 months after surgery during implant surgery, a piece of soft tissue is punched at the implant site and sent to the laboratory to examine the histological characteristics of the soft tissue.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Periodontics, Dental Clinic, Tabriz University of Medical Sciences and Health Services
Full name of responsible person
Amirreza Babaloo
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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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
Amir reza Babaloo
Position
Assistant Professor

Latest degree
Ph.D.
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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available