Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of Aoutologus Conditioned Serum on histological and radiographic characteristics of hard tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Protocol summary

Study aim

The aim of this study was to improve the characteristics of bone tissue in the site of implant placement and to investigate the effect of Autologous Conditioned Serum on histological and radiographic characteristics of hard tissue after Horizontal Bone Augmentation or Socket preservation in Tabriz University of Medical Sciences.

Design

This clinical trial has a control group, with parallel groups, single blinded, randomized, phase 3 on 21 patients. In this study, the control and intervention group will be one group and two areas of oral hard tissue will be considered as control and intervention.

Settings and conduct

Study place: Department of Periodontics, Dental Clinic, Tabriz University of Medical Sciences and Health Services

Participants/Inclusion and exclusion criteria

Inclusion criteria: The difficulty of surgery based on the dimensions required for agmentation, as well as the condition of the existing tooth before extraction and the condition of the ridge of one side compared to the other side should be the same, patients should require implant placement in the area and satisfied to surgery. Exclusion criteria: use of drugs that may interfere with the treatment process, the presence of systemic disease, smokers, inflammation or infection or pain during surgery, recent history of use of nonsteroidal anti-inflammatory drugs, patients with gastrointestinal problems, allergies to NSAIDs and pregnancy

Intervention groups

intervention group Includes placement of an ACS-impregnated membrane in the postoperative area. Control Group includes placement of a membrane without ACS in the postoperative area.

Main outcome variables

Alkaline phosphatase activity, Tissue mineralization rate, Number of cells per unit area, Collagen content Gene expansion, Horizontal dimension of bone, Hansfield number

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180905040955N2**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **retrospective**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date

2022-01-09, 1400/10/19

Registrant information

Name

Hamidreza Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aoutologus Conditioned Serum on histological and radiographic characteristics of hard tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Public title

Evaluation of the effect of orthokine on histological and radiographic characteristics of hard tissue after Horizontal Bone Augmentation and Socket Preservation surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The difficulty of surgery is the same compared to the other side based on the dimensions required for augmentation as well as the condition of the existing tooth before extraction and the condition of the ridge. Patients should require implant placement in site patients should be satisfied for surgery.

Exclusion criteria:

presence of systemic diseases presence of history of using disruptive drugs in healing processes The patient does not want to have surgery Presence of metabolic bone diseases

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **21**

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. None of the patients were informed about the treatment of another patient. The evaluator was not aware of the type of treatment.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only the facilitator (supervisor) who is not involved in the collection and analysis of study data and the researcher who will place the material in two areas of the oral hard tissue will be aware of the study groupings and the researcher, the data analyzer And the test subject will be blinded. The study will be performed single blinded. In fact, the test subject will not be aware of the use of ACS in the surgical area.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

Daneshgah st,Faculty of dentistry

City

Tabriz

Province

East Azarbaijan

Postal code

5711593886

Approval date

2021-06-21, 1400/03/31

Ethics committee reference number

IR.TBZMED.REC.1400.291

Health conditions studied

1

Description of health condition studied

Horizontal Bone Augmentation

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Socket preservation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Alkaline phosphatase activity

Timepoint

4 months after surgery

Method of measurement

MultiSkanGo plate reader software

2

Description

issue mineralization rate

Timepoint

4 months after surgery

Method of measurement

Investigation of mineralized areas in histological slide examination

3

Description

Number of cells per unit area

Timepoint

4 months after surgery

Method of measurement

Histological slide examination and MutikImage 2 software

4

Description

The amount of collagen

Timepoint

4 months after surgery

Method of measurement

Hematoxylin and eosin staining and TRAP, histological slide examination

5

Description

gene expansion

Timepoint

4 months after surgery

Method of measurement

Reverse transcription PCR

6

Description

Horizontal dimension of bone

Timepoint

4 months after surgery

Method of measurement

Calculation from CBCT radiography

7

Description

Hansfield number

Timepoint

4 months after surgery

Method of measurement

Calculation from CBCT radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: According to the goal, 21 people will be studied to prove the hypothesis and achieve the desired goal. After preparing the volunteer patient psychologically and explaining the goals of the project and the cases of cooperation, written consent, CBCT radiographic image of the patient will be obtained and preoperative radiographic evaluations will be performed. One day before surgery 10 cc Blood will be prepared from the patients vein and immediately inject into a special orthokine syringe. The syringe will be then placed in an incubator at 37 ° C for 8 hours and then enters the centrifuge (3000 rpm for 10 minutes). After the centrifuge, the syringe will be removed from the machine and enters the 0.2 filter, then the syringe has two parts, The upper part will be carefully removed by syringe and will be stored as ACS in the refrigerator and will be used in site on the day of surgery. After local anesthesia injection and ensuring anesthesia, the patient will undergo horizontal bone augmentation surgery in the area. The incision will be done done using a blade No. 15 and crestal incision in the area will be created .Soft tissue will be elevated using periost elevators and site will be prepared to the placement of the ACS impregnated membrane . The collagen membrane with a thickness of 1.1 to 1.4 (Hamanand saz baft kish inc) will be impregnated with 1 ml ACS and 1 cc allogeneic bone graft 500 to 100 microns will be placed in the site. Soft tissue will be returned and sutured using 3-0 silk thread. The patients medications include chlorhexidine mouthwash, acetaminophen, and the patient will be advised after surgery. 4 months after surgery, the area for implant placement is evaluated. To examine the histological changes, after flap elevation in the observed areas for implant placement by crestal incision using blade number 15, bone samples will be removed from the implant placement area with the help of Meisingers trephine bur with a diameter of 1.1 mm and immediately placed in formalin. The above samples will be transferred to the histological laboratory to evaluate: 1. Alkaline phosphatase activity, 2. Tissue mineralization, 3. Number of cells per unit area (osteoblasts, osteoclasts, fibroblasts and inflammatory cells) and 4. Collagen amount (hematoxylin and eosin and alizarin staining red) .Also the samples will be sent to the medical genetics laboratory to evaluate Gene expansion (Type I collagen alpha1, Alkaline phosphatase, Osteocalcin, Runx 2, RANKL, GAPDH, OPG) .The CBCT radiograph will be taken and the radiographic evaluation of the changes in the two areas will be calculated using the amount of bone formed in the horizontal dimension as well as the Hansfield number.

Category

Treatment - Drugs

2

Description
Control group: According to the goal, 21 people will be studied to prove the hypothesis and achieve the desired goal. After preparing the volunteer patient psychologically and explaining the goals of the project and the cases of cooperation, written consent, CBCT radiographic image of the patient will be obtained and preoperative radiographic evaluations will be performed. After local anesthesia injection and ensuring anesthesia, the patient will undergo horizontal bone augmentation surgery in the area. The incision will be done done using a blade No. 15 and crestal incision in the area will be created .Soft tissue will be elevated using periost elevators and site will be prepared to the placement of the membrane . The collagen membrane with a thickness of 1.1 to 1.4 (Hamanand saz baft kish inc) and 1 cc allogeneic bone graft 500 to 100 microns will be placed in the site. Soft tissue will be returned and sutured using 3-0 silk thread. The patients medications include chlorhexidine mouthwash, acetaminophen, and the patient will be advised after surgery. 4 months after surgery, the area for implant placement is evaluated. To examine the histological changes, after flap elevation in the observed areas for implant placement by crestal incision using blade number 15, bone samples will be removed from the implant placement area with the help of Meisingers trephine bur with a diameter of 1.1 mm and immediately placed in formalin. The above samples will be transferred to the histological laboratory to evaluate: 1. Alkaline phosphatase activity, 2. Tissue mineralization, 3. Number of cells per unit area (osteoblasts, osteoclasts, fibroblasts and inflammatory cells) and 4. Collagen amount (hematoxylin and eosin and alizarin staining red) .Also the samples will be sent to the medical genetics laboratory to evaluate Gene expansion (Type I collagen alpha1, Alkaline phosphatase, Osteocalcin, Runx 2, RANKL, GAPDH, OPG) .The CBCT radiograph will be taken and the radiographic evaluation of the changes in the two areas will be calculated using the amount of bone formed in the horizontal dimension as well as the Hansfield number.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental School,Tabriz university of medical sciences
Full name of responsible person
Adileh Shirmohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
vice chancellery for research and technology of tabriz university of medical sciences
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East Azarbaijan
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor of research of Tabriz university of medical sciences
Proportion provided by this source
80
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
Adileh Shirmohammadi
Position
professor
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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
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