

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of Concentrated Growth Factor (CGF) on healing outcome in maxillary sinus graft (histological examination)

Protocol summary

Study aim

the effect of Concentrated Growth Factor(CGF) on healing outcome in maxillary sinus graft(histological examination)

Design

Clinical trial with parallel group, single-blind, randomized, phase 3 on 9 patients. The randomization method is simple and the unit is individual.

Settings and conduct

9 patients referring to Tabriz Dental School will enter the study. The patient's sinuses will be treated using the open lift technique and randomly placed CGF in a sinus and xenograft used in the other. After 6 months, the histological sample from the osteotomy site will be prepared and histological examination will be performed. The examiner does not know the type of sample sent to the laboratory.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of bilateral posterior partial edentulousness or complete maxillary edentulousness; The remaining bone height between the alveolar crest and the sinus floor is less than 5mm . Exclusion criteria: Smokers; Pregnant women; Presence of pathological symptoms, cystic lesions, acute and chronic inflammatory disease, benign and malignant tumors in the sinus; Existence of systemic diseases such as uncontrolled diabetes, cardiovascular disease, malignancy, head and neck radiotherapy; Autoimmune diseases that make soft and hard tissue repair difficult 6.Use of steroid drugs and immunosuppressants - bisphosphonates; Existence of untreated and periapical periodontal diseases, especially in the teeth adjacent to the sinus floor

Intervention groups

1) CGF is placed in the sinus of one side 2) Xenograft is used in the sinus on the other side of the same patient

Main outcome variables

The amount of formed bone; The amount of remained graft material

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201215049728N1**

Registration date: **2021-01-09, 1399/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Mohammad taghi Chitsazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7314

Email address

mtchitsazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Concentrated Growth Factor (CGF) on healing outcome in maxillary sinus graft (histological examination)

Public title

The effect of a growth factor on restoration results in maxillofacial lift

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of bilateral posterior partial edentulousness or complete maxillary edentulousness The remaining bone height between the alveolar crest and the sinus floor is less than 5mm

Exclusion criteria:

Smokers Pregnant women Presence of pathological symptoms, cystic lesions, acute and chronic inflammatory disease, benign and malignant tumors in the sinus Existence of systemic diseases such as uncontrolled diabetes, cardiovascular disease, malignancy, head and neck radiotherapy Autoimmune diseases that make soft and hard tissue repair difficult Use of steroid drugs and immunosuppressants - bisphosphonates Existence of untreated and periapical periodontal diseases, especially in the teeth adjacent to the sinus floor

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **9**

More than 1 sample in each individual

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

14 maxillary sinus samples were obtained from 7 patients. To increase the validity of the study, 20% was added to the sample size, and finally 18 sinuses from 9 patients were considered.

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is random among the people referring to the Tabriz Dental School. The randomization method is simple and the unit is individual. To do this, the types of treatment are identified with code A (Growth factor) and B(Xenograft), and then will be placed in sealed envelopes and will be stirred. Then they are randomly taken out of the bag and after observing the code, the desired treatment will be given to the right side and the other treatment will be given to the left side of the patient's mouth.

Blinding (investigator's opinion)

Single blinded

Blinding description

Samples prepared from individuals are sent as coded form to the laboratory. The examiner (histologist) has no

knowledge of the type of intervention.

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

3rd floor, No2 Central Building , Tabriz University of Medical Sciences, ,Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.TBZMED.REC.1399.845

Health conditions studied

1

Description of health condition studied

Dental implants

ICD-10 code

Z96.5

ICD-10 code description

Presence of tooth-root and mandibular implants

Primary outcomes

1

Description

The amount of newly formed bone

Timepoint

6 months after treatment

Method of measurement

Histological specific staining (Hematoxylin and Alizarin red)

Secondary outcomes

1

Description

The remaining amount of graft material

Timepoint

6 months after treatment

Method of measurement

Histological specific staining (Hematoxylin and Alizarin red)

Intervention groups

1

Description

Intervention group 1: Concentrated growth factor (CGF) is placed in the sinus and after 6 months, a histological sample will be prepared from the osteotome site with a 2.7mm narrow terpene milling machine and will be sent to the histological laboratory for examination.

Category

Treatment - Other

2

Description

Intervention group 2: A xenograft is placed in the sinus on the other side of Navateb Pars Company and after 6 months, a histological sample from the osteotome site will be prepared with a 2.7mm narrow terpene milling machine and will be sent to the histology laboratory for examination.

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tabriz University of Medical Sciences, School of Dentistry

Full name of responsible person

Mohammadtaghi Chitsazi

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3rd floor, No2 Central Building , Tabriz University of Medical Sciences, ,Golgasht street

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

Mohammadtaghi Chitsazi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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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