

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of adipose tissue - mononuclear cells (AT-NMCs) on maxillofacial bone regeneration: a randomized, controlled clinical trial and phase 1

Protocol summary

Study aim

The main objective of this study is evaluating the safety of using mononuclear cells isolated from adipose tissue to regeneration bone tissue in patients with an oral maxillofacial bone defect after 6 months from surgery.

Design

A clinical trial with a control group, parallel, randomized

Settings and conduct

The present study provides a cell therapy approach for improvement of bone regeneration in oral-maxillofacial defects. the study will be performed in the Ayatollah Taleghani Hospital, Shahid Beheshti University of medical sciences. Twenty patients with an oral-maxillofacial defect will be selected randomly based on inclusion and exclusion criteria. After general anesthesia, in the test group, adipose tissue will be harvested and mononuclear cells isolated by mechanical method during the surgery. Then cells will be transplanted to defect site along with routine scaffold. Patients in the control group will have surgery by implantation only scaffold in the defect site, as a routine technique. moreover, blinding was no performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -The patient has a bone defect in the maxillofacial region non-inclusion criteria: -The defect should not be socket, dehiscence, fenestration, and also sinus not involved. -systemic and metabolic diseases - active infection -compromised immune system -pregnant and or lactating women -osteoporosis and osteopetrosis - previous alveolar surgery -smoking

Intervention groups

intervention group: the transplantation mononuclear cell isolation of fat tissue autologous and bone scaffolds to improve defect bone in the oral maxillofacial region
control group: the transplantation bone graft to defect bone in the oral maxillofacial region

Main outcome variables

the primary outcome of this trial is safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041860N1**

Registration date: **2019-09-26, 1398/07/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-26, 1398/07/04**

Update count: **0**

Registration date

2019-09-26, 1398/07/04

Registrant information

Name

Mahboubeh Bohlouli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2243 9848

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bohlouli98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-27, 1398/06/05

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of adipose tissue - mononuclear cells (AT-NMCs) on maxillofacial bone regeneration: a randomized, controlled clinical trial and phase 1

Public title

Providing a therapeutic method for regeneration of damaged bone tissue in the oral and maxillofacial region by mononuclear cells isolated from the patient's own fat tissue

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient has a bone defect in the maxillofacial region

Exclusion criteria:

The defect should not be socket, dehiscence, fenestration, and also sinus not involved. systemic and metabolic diseases active infection compromised immune system pregnant and or lactating women osteoporosis and osteopetrosis previous alveolar surgery smoking

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization is performed using the block method using SAS software. twenty patient will be involved in the study, which will be classified into two groups. to avoid identifying the last patient by medical staff, 5 blocks with 6 wells will be designed that only 4 wells per each block will be considered. To conceal randomization, each block will be placed in an envelope and all researchers will unaware of the contents of the envelopes. Therefore, a non-study individual was selected to perform all these steps to inform the physician of the result.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of shahid beheshti university of medical science

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arabi

City

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Province

Tehran

Postal code

1985717443

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.SBMU.REC.1398.061

Health conditions studied**1****Description of health condition studied**

Patients with maxillofacial bone defects

ICD-10 code

M89.3

ICD-10 code description

Hypertrophy of bone

Primary outcomes**1****Description**

in this study, safety is the main primary outcome.

Timepoint

The patient will be visited one and six days as well as 1 and 6 months after surgery. But during this time, if patients have any abnormal clinical symptoms, you will be counseled or visited by telephone or in person.

Method of measurement

To evaluate the safety, different parameters such as infection, inflammation, fibrosis tissue formation, local edema, local erythema, pain, dental implant rejection, dental sensitivity, and mortality will be evaluated through clinical evaluations, blood tests, CT scans Conical scans and scatological analyzes.

Secondary outcomes**1****Description**

New bone formation

Timepoint

after 6 months from surgery

Method of measurement

analysis of Cone Beam-CT data and histology images

Intervention groups

1

Description

Intervention group: Patients with oral maxillofacial bone defect who receive autologous mononuclear cells isolated from adipose tissue with bone scaffolds (routine treatment) through oral maxillofacial surgery

Category

Treatment - Surgery

2

Description

Control group: Patients with oral maxillofacial bone defect who receive bone scaffolds (or routine treatment) through oral maxillofacial surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

ayatollah taleghani hospital

Full name of responsible person

دکتر آرش خجسته

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahboubeh Bohlouli

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available