Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of the effect of a 3D printed biocompatible composite scaffold customized for the patient with the use of buccal fat pad micrograft on regeneration of bone defects in the patients with palatal and alveolar bone cleft

Protocol summary

Study aim

The aim of the current study is to fabricate a customized biocompatible 3D printed scaffold and use in combination with BFP- SVF for human alveolar cleft reconstruction.

Design

Phase 1 of clinical trial with control group and one-sided blind with no randomization on 10 patients

Settings and conduct

Patients referred to Ayatollah Taleghani Hospital (Tehran, Iran) are selected according to the inclusion and exclusion criteria. By an experienced oral and maxillofacial surgeon and under general anesthesia the test patients are treated by the 3D printed customized scaffold with buccal fat pad micro graft, and the control patients by autogenous iliac bone graft. CBCT images obtained 6 months after the surgery are evaluated by an experienced blind radiologist.

Participants/Inclusion and exclusion criteria

The inclusion criteria include: 1. patient with alveolar or palatal cleft, 2. Defect size more than 2 cm3, 3. Soft tissue deficiency is not seen, 4. Maxillary sinus is not involved, 5. Dental dehiscence or fenestration is not seen. The exclusion criteria include: 1. Autoimmune or metabolic or systemic diseases 2. Peripheral vascular diseases, 3. Marble bone disease or osteoporosis, 4. Smoking or alcohol consumption, 5. Conditions which compromise wound healing process, 6. Being in breastfeeding or pregnancy.

Intervention groups

1. Alveolar cleft treated by the 3D printed composite scaffold with buccal fat pad micrograft 2. Alveolar cleft treated by autogenous iliac bone graft

Main outcome variables

In the previous cleft region, height, width, and length of the alveolar ridge, newly formed bone density, bone to construct contact are evaluated. In histologic analysis, the rate of new bone formation, the rate of fibrosis or necrosis (if seen), foreign body reaction (if seen), and the rate of remained scaffold are evaluated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191002044949N1**
Registration date: **2022-01-11, 1400/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-11, 1400/10/21**
Update count: **0**

Registration date

2022-01-11, 1400/10/21

Registrant information

Name

Farshid Bastami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5350

Email address

farshidbst@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-20, 1400/01/31

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of a 3D printed biocompatible composite scaffold customized for the patient with the use of buccal fat pad micrograft on regeneration of bone defects in the patients with palatal and alveolar bone cleft

Public title

Reconstruction of palatal cleft using 3D printer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with alveolar or palatal cleft Defect size more than 2 cm3 soft tissue deficiency is not seen maxillary sinus is not involved Dental dehiscence or fenestration is not seen

Exclusion criteria:

autoimmune or metabolic or systemic diseases peripheral vascular diseases marble bone disease or osteoporosis smoking or alcohol consuption conditions which compromise wound healing process being in breastfeeding or pregnancy

Age

From **10 years** old

Gender

Both

Phase

1

Groups that have been masked

- Investigator

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The investigators has not been informed about the patients' code. Investigators include a radiologist for obtaining CBCT and a person who evaluate informations by Materialise Mimics (3D Medical Image Processing Software).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, School of Dentistry, Shahid Beheshti Univerisity of Medical Sciences

Street address

Evin, Daneshju boulevard

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2019-06-17, 1398/03/27

Ethics committee reference number

IR.SBMU.DRC.REC.1398.123

Health conditions studied

1

Description of health condition studied

Maxillary alveolar cleft

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Height, width and length of the ridge at the alveolar defect site in test group in comparison with the control group

Timepoint

6 month after surgery

Method of measurement

CBCT scan

2

Description

New formed bone density at the alveolar defect site in test group in comparison with the control group

Timepoint

6 month after surgery

Method of measurement

Radio morphometry using CBCT scan

3

Description

Native bone and scaffold contact at the alveolar defect site in test group in comparison with the control group

Timepoint

6 month after surgery

Method of measurement

CBCT scan

4

Description
The rate of new bone formation at the alveolar defect site in test group in comparison with the control group
Timepoint
6 month after surgery
Method of measurement
Histologic assessment by H&E staining

5

Description
The rate of fibrosis or necrosis if exists at the alveolar defect site in test group in comparison with the control group
Timepoint
6 month after surgery
Method of measurement
Histologic assessment by H&E staining

6

Description
Foreign body reaction if exists at the alveolar defect site in test group in comparison with the control group
Timepoint
6 month after surgery
Method of measurement
Histologic assessment by H&E staining

7

Description
The rate of scaffold remnants if exists at the alveolar defect site in test group in comparison with the control group
Timepoint
6 month after surgery
Method of measurement
Histologic assessment by H&E staining

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Gelatin (5-20 wt%)/ alginate (1-4 wt%)/ allograft (10-40 wt%) in combination with buccal fat pad micrograft. Gelatin with medical grade is purchased from Nitta Gelatin Co, China, Alginate with medical grade from KIMICA co, Japan, and allograft bone powder from Iranian Tissue Product company (RegenTM). Buccal fat pad micrograft is obtain by using a novel mechanical device, called Minceolip, was patented by our team in the Intellectual Property Office of Real Estate Registration Organization of Iran (Application Number 13985040003006638). Safety of Buccal fat pad micrograft was performed clinically according to a study approved by the Ethical Committee of the Shahid Beheshti University of Medical Sciences (Approval number IR.SBMU.REC.1398.061), and Iranian Registry of Clinical Trials (IRCT) with IRCT code 20181205041860N1 on September 26, 2019.
Category
Rehabilitation

2

Description
Control group: Autogenous bone graft harvested from anterior crest of iliac bone which is the gold standard treatment of alveolar bone defects reconstruction.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani Hospital
Full name of responsible person
Arash Khojasteh
Street address
Shahid Aarabi street, Evin
City
Tehran
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Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Fax
+98 21 2243 2570
Email
taleghanihospital@sbmu.ac.ir
Web page address
https://taleghani.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Evin, Shahid Aarabi street
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Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9781

Fax
+98 21 2243 9981
Email
Mpajouhesh@sbmu.ac.ir
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
Farshid Bastami
Position
Oral and Maxillofacial Surgery resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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arashkhojasteh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only demographic factors information such as age and

gender, and CBCT images and clinical views of surgery can be shared by a scientific article when the patient is unidentifiable.

When the data will become available and for how long

The data will become available 6 months after publication.

To whom data/document is available

All researchers can apply to receive the data.

Under which criteria data/document could be used

It is possible for researchers to use our data or documentation to conduct research and clinical studies while maintaining ethical conditions.

From where data/document is obtainable

Applicants can contact Dr. Farshid Bastami with the following information and express their application: Email: farshidbst@gmail.com Tel: 00989126704434

What processes are involved for a request to access data/document

Applicants must submit a clear length of the email and submit their application. After evaluating the applicant and his/her request, he/she will be given an appropriate response at the earliest time (at least after a week).

Comments