

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Fabrication and Clinical trial of biodegradable composite meshes manufactured through additive manufacturing for application in orbital fracture and cleft palate

Protocol summary

Study aim

Clinical evaluation of hydroxyapatite and polycaprolactone surgical mesh fabricated via 3D printing method for cleft palate disorders or orbital floor fractures

Design

This is a non randomized single group clinical trial with 7 patients receiving 3D printed surgical mesh enrolling between March 2023 and March 2024, and will be followed for six months after the surgery.

Settings and conduct

The prepared surgical mesh will be used in 7 patients. After implant placement and fixation, the skin will be sutured. In 7 to 10 days after surgery, a clinical evaluation of the patient will be performed. In 3 and 6 months after surgery, CT scan images will be provided to examine the bone regeneration and implant degradation ratio.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are suffering from congenital cleft palate disorders and due to the wide gap between the palate usual surgical techniques cannot be applied or patients with traumatic injuries to orbital floor of the skull. Exclusion criteria: Having an underlying disease, including allergies.

Intervention groups

The diagnostics for this intervention include patients who suffer from cleft palate congenital disorders or patients who have suffered from a traumatic accident and are diagnosed with orbital fractures. During a cranioplasty surgery a 3D-printed mesh will be implanted on the cleft palate opening or will be used to repair the orbital floor fracture. The printed mesh will be fabricated from polycaprolactone and hydroxyapatite compounds by Adli Tissue Regeneration company.

Main outcome variables

close the gap in the roof of the mouth and

rearrangement of the muscles and the lining of the palate; orbital floor fracture repair; natural patient ingrowth within the implant's structure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220807055633N2**

Registration date: **2023-02-25, 1401/12/06**

Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**

Update count: **0**

Registration date

2023-02-25, 1401/12/06

Registrant information

Name

Seyed Ali Poursamar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3865

Email address

ali.poursamar@amt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-11, 1401/12/20

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fabrication and Clinical trial of biodegradable composite meshes manufactured through additive manufacturing for application in orbital fracture and cleft palate

Public title

Clinical trials of 3D printing in fabrication of prosthesis for regeneration of cleft palate disorders or orbital fracture

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People who have skull and face defects and the use of plates in surgery cannot correct the shape of the bone.

Exclusion criteria:

Having an underlying disease, including allergies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 7

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Esfahan University of Medical Sciences

Street address

Hezar Jerib Avenue

City

esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-12-26, 1401/10/05

Ethics committee reference number

IR.ARI.MUI.REC.1401.251

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

Flexible surgical mesh for cleft palate repair

ICD-10 code

Q35.9

ICD-10 code description

Cleft palate, unspecified

2**Description of health condition studied**

Flexible surgical mesh for orbital fracture repair

ICD-10 code

S02.3

ICD-10 code description

Fracture of orbital floor

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

close the gap in the roof of the mouth and rearrangement of the muscles and the lining of the palate

Timepoint

2 weeks and 4 months after the surgery

Method of measurement

in person patient examination

2**Description**

Orbital floor fracture repair

Timepoint

3 and 6 months after the surgery

Method of measurement

in person patient examination and CT-scan imaging

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

natural patient ingrowth within the implants structure

Timepoint

6 months after the surgery

Method of measurement

CT scan imaging and in person patient examination

Intervention groups

1

Description

Intervention group: The diagnostics for this intervention include patients who suffer from cleft palate congenital disorders or patients who have suffered from a traumatic accident and are diagnosed with orbital fractures. During a cranioplasty surgery a 3D-printed mesh will be implanted on the cleft palate opening or will be used to repair the orbital floor fracture. The printed mesh will be fabricated from polycaprolactone and hydroxyapatite compounds by Adli Tissue Regeneration company.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Esfahan University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Seyed Ali Poursamar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Engineering

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable