

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Clinical study of patient-specific bone implant prepared via 3D printing method for craniofacial surgery applications

Protocol summary

Study aim

Clinical evaluation of hydroxyapatite and polycaprolactone implants prepared via 3D printing method for craniofacial surgery applications

Design

It is a non randomized single group clinical trial with 7 patients receiving 3D printed craniofacial implants enrolling between April 2022 and February 2023, and will be followed for six months.

Settings and conduct

The prepared implants 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

Patients over 6 years old who suffer from craniofacial defects and the use of plates in surgery cannot correct the shape of the bone. Exclusion criteria: Having an underlying disease, including allergies.

Intervention groups

The intervention group is investigating the effectiveness and durability of 3D printed implants made of polycaprolactone and hydroxyapatite (40% wt). These implants are intended for trauma patients or patients with natural birth defects with bone deformities in the skull and face area. Implants will be administered during surgery after general anesthesia. The implants are prepared in collaboration with Adli Tissue Regeneration company.

Main outcome variables

Newly formed bone density; the rate of new bone formation; biodegradation rate of the implant; patient sensitivity to ambient temperature changes;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220807055633N1**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-16, 1401/06/25**

Update count: **0**

Registration date

2022-09-16, 1401/06/25

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

2022-07-31, 1401/05/09

Expected recruitment end date

2023-01-29, 1401/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of patient-specific bone implant prepared via 3D printing method for craniofacial surgery applications

Public title

Evaluation of 3D printed bone implant in skull and the face surgery

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

From **20 years** old

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

2022-07-31, 1401/05/09

Ethics committee reference number

IR.ARI.MUI.REC.1401.132

Health conditions studied

1

Description of health condition studied

Absorbable bone implants to correct craniofacial abnormalities

ICD-10 code

Z96.7

ICD-10 code description

Presence of other bone and tendon implants

Primary outcomes

1

Description

New bone formation

Timepoint

3 and 6 months after implant placement

Method of measurement

Providing CT scan images

Secondary outcomes

1

Description

biodegradation rate of the implant

Timepoint

3 and 6 months after implant placement

Method of measurement

Providing CT scan images

Intervention groups

1

Description

Intervention group: Personalized 3D printed biodegradable implants comprised of polycaprolactone and hydroxyapatite (40% Wt) made by Adli Tissue Regeneration company are utilized during surgery for patients who suffer from bone abnormalities in the skull and face.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan University of Medical Sciences

Full name of responsible person

Seyed Ali Poursamar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Askari

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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

Tissue Engineering

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Latest degree

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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