Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

Safety and Efficacy of Acellular Dermal Graft (ADG) in Orbital Fracture Repair; A Pilot Study

Protocol summary

Study aim
1- Evaluation of ADG safety in orbital fracture repair 2- Evaluation of ADG efficacy in orbital fracture repair

Design
This clinical trial (pilot study) will be conducted on 10 patients prospectively.

Settings and conduct
This study is conducted in Rasoul Akram Hospital on patients who come to the hospital with orbital trauma and have an indication for surgical repair of orbital fracture. Surgery will be performed under general anaesthesia. The surgeon will use transconjunctival method to place ADG in fractured area .The patient will be visited at first and seventh days after operation. the study data will be collected at one month, three months and six months after surgery.

Participants/Inclusion and exclusion criteria
Fracture of the orbital floor or medial wall with one of the following characteristics: Fractures more than 50% of the orbital floor Muscle entrapment Significant enophthalmus Significant hypoglobus

Intervention groups
In this study, ADG is used for orbital fracture repair in patients with orbital wall fracture who are subject to the inclusion criteria. This study dose not have a control group.

Main outcome variables
Evaluation of the enophthalmos; hypoglobus; eye movements and diplopia; visual acuity correction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220424054640N3**
Registration date: **2022-09-16, 1401/06/25**
Registration timing: **prospective**
Last update: **2022-09-16, 1401/06/25**
Update count: **0**

Registration date
2022-09-16, 1401/06/25

Registrant information

Name
Nasser Karimi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 912 327 2376

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-22, 1401/06/31

Expected recruitment end date
2024-03-18, 1402/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and Efficacy of Acellular Dermal Graft (ADG) in Orbital Fracture Repair; A Pilot Study

Public title
Safety and Efficacy of Acellular Dermal Graft in Orbital Fracture Repair

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Fracture of the orbital floor or medial wall with one of the following characteristics: Fractures more than 50% of the orbital floor Muscle entrapment Enophthalmus that affecting cosmetic issues Hypoglobus that affecting cosmetic issues

Exclusion criteria:

Patients who previously underwent orbital surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

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 Iran university of medical sciences

Street address

Eye Research Center of Iran University: 8th Floor, Seyed al-Shohada Building, Hazrat Rasool hospirtal, Niayesh St., Sattar Khan St., Tehran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2022-08-08, 1401/05/17

Ethics committee reference number

IR.IUMS.REC.1401.431

Health conditions studied

1

Description of health condition studied

Inferior wall fracture of orbit

ICD-10 code

S02.3

ICD-10 code description

fracture of orbital floor

2

Description of health condition studied

medial wall fracture of orbit

ICD-10 code

S02.83

ICD-10 code description

Fracture of medial orbital wall

Primary outcomes

1

Description

The amount of correction of eye motility

Timepoint

One month, three months and six months after surgery

Method of measurement

examination

2

Description

The amount of correction of hypoglobus

Timepoint

One month, three months and six months after surgery

Method of measurement

Neugle exophthalmometer

3

Description

The amount of correction of enophthalmus

Timepoint

One month, three months and six months after surgery

Method of measurement

Hertel exophthalmometer

4

Description

Prevalence of reactive symptoms to alloplastic material

Timepoint

One month, three months and six months after surgery

Method of measurement

History and examination

5

Description

The degree of orbit inflammation and infection

Timepoint

One month, three months and six months after surgery

Method of measurement

History and examination

6

Description
The amount of implant protrusion
Timepoint
One month, three months and six months after surgery
Method of measurement
Examination and CT scan

7

Description
The rate of visual function loss: visual acuity
Timepoint
One month, three months and six months after surgery
Method of measurement
snallen chart

8

Description
The rate of visual function loss: Marcus Gunn's pupil
Timepoint
One month, three months and six months after surgery
Method of measurement
examination with muscle light

9

Description
The rate of visual function loss: visual field
Timepoint
One month, three months and six months after surgery
Method of measurement
Humphrey visual field: 24-2 SITA standard

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: All patients will undergo examination and recording of visual acuity, eye movements and exophthalmometery before surgery. CT-scan is performed for all patients before surgery. patients who subject the inclusion criteria will fill the consent form. then a piece of ADG will be ordered from Danesh Banyan company.The nature of Acellular dermal graft (ADG): ADG is processed from donated human dermis and contains collagen and elastin fibers. This product is cell-free due to enzymatic and chemical process. The antigenic property of the product has been removed, but the natural structure of collagen fibers, elastin, basement membrane and its three-dimensional structure are preserved and it is suitable for tissue repair, implantation and proliferation of fibroblasts. This product has two surfaces: a base membrane that prevents the penetration of pathogens into the underlying layers and a skin surface that stimulates Neo-vascularization and connection, stimulation and proliferation of fibroblasts. After providing ADG, according to clinic routines, the patient will go through pre-op anaesthesia proceedings and surgery appointment then will undergo surgery. The surgery will be performed under general anesthesia. The surgeon dose dissection by the transconjunctival method until reaching the lower orbit rim, then the arcus marginalis will be cut and the peri-orbita will be lifted by the elevator. In this way, the extension and location of the fracture is identified and the surgeon will cut a piece of ADG corresponding to the size of the fracture and cover the fracture site. At the end, the peri-orbita will be sewn in place by Vicryl 6.0, and rectus muscles will be checked with forced duction test. After surgery, betamethasone and clobiotic drops four times in a day for one week and oral prednisolone 1 mg/kg with cephalexin 250 mg every 6 hours for five days will prescribed. The patient will be visited at first and seventh day after the operation, and the study data will be collected one month, three months and six months after surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasool hospirtal
Full name of responsible person
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nasser Karimi
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
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