

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison complication Of Hydroxyapatite and Medpor Ocular Implant Insertion After Enucleation In Ahwaz Imam Hospital (from jan 2010 to jun2011)

Protocol summary

Summary

Comparison complication of Hydroxyapatite and Medpor ocular implant insertion after enucleation in Ahwaz imam hospital (from jan 2010 to jun 2011) . All patients over 18 months (from jan 2010 until June 2011) in Ahwaz Imam Khomeini Hospital who have loss of vision for different reasons have been under surgery to enucleation with the implant insertion. exclusion criteria :eye lid disorders such as entropion;trichiasis; ectropion ; cul-de-sac problems before surgery ;anophthalmus;conjunctival ;eyelid malignancies.in a clinical trial study 50 patients that had indication for enucleation randomly divided in two groups of 25 patients group 1 under went enucleation + hydroxyapatite (HA) and group 2 underwent enucleation + medpor implant, all patients were operated by 2 surgeons then were followed for 6 months and complications were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205139729N1**
Registration date: **2012-06-25, 1391/04/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-25, 1391/04/05

Registrant information

Name

Safar Mohamadzadeh

Name of organization / entity

Ahwaz University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahwaz University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-07-21, 1390/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison complication Of Hydroxyapatite and Medpor Ocular Implant Insertion After Enucleation In Ahwaz Imam Hospital (from jan 2010 to jun2011)

Public title

Comparison Complication Of Hydroxyapatite and Medpor Ocular Implant Insertion.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Loss of vision ;Enucleation with the implant insertion. Exclusion criteria :Eye lid disorders such as Entropion;Trichiasis; Ectropion ; cul-de-sac problems before surgery ;Anophthalmus;Conjunctival ; Eyelid malignancies

Age

No age limit
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: 50
Randomization (investigator's opinion)
Randomized
Randomization description
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

Ahwaz University of Medical Science .

Street address

Ahwaz Univercity of Medical Science , University town
, Ahwaz

City

Ahwaz

Postal code

61357-15794

Approval date

2009-07-15, 1388/04/24

Ethics committee reference number

1912//20/8/پ

Health conditions studied

1

Description of health condition studied

Comparison complication of two method of eye
enuclation and implant insersion

ICD-10 code

H53-H54

ICD-10 code description

Visual disturbances and blindness

Primary outcomes

1

Description

Mucupurulent discharge
Timepoint
10,30,90,180
Method of measurement
Examination with slitlamp

Secondary outcomes

1

Description

granulom tissue

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

2

Description

conjunctival cyst

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

3

Description

cul-de- sac limitation

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

4

Description

Range of eye movements

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

5

Description

Implant expuser

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

6

Description

Eyelid edema

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

7

Description

conjunctival chemosis

Timepoint

10th,30th,90th,180th day

Method of measurement

Examination with slit lamp

Intervention groups

1

Description

surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hospital

Full name of responsible person

Street address

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor of Ahwaz University of Medical Science

Full name of responsible person

Mostafa Feghi

Street address

Ahwaz University of Medical Sciences , University Town , Ahwaz

City

Ahwaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Vice Chancellor of Ahwaz University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Ghaderpanah Mahboobe

Position

Associated Professor

Other areas of specialty/work

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Contact

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Person responsible for updating data

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Mohamadzadeh Safar

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty