Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Study the effect of early vitrectomy on visual acuity of patients with endophthalmitis

Protocol summary

Study aim
Determine the effect of early vitrectomy on patients with Endophthalmitis
Design
Single arm clinical trial, with 24 patients, enrolled between November 2020 and March 2021, and will be followed for 3 months. Randomization and Blinding is not applicable.
Settings and conduct
This study will be performed in Feiz hospital, Isfahan, Iran. Patients will be included based on inclusion and exclusion criteria. Visual acuity of patients will be assessed at base line, one and three months after the intervention.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with endophthalmitis after cataract surgery; Exclusion criteria: patients who receive inter-vitreous antibiotics injection
Intervention groups
Intervention group: In intervention group, early vitrectomy will be performed
Main outcome variables
Visual acuity, Retinal detachment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201103049247N1**
Registration date: **2020-11-15, 1399/08/25**
Registration timing: **prospective**

Last update: **2020-11-15, 1399/08/25**
Update count: **0**
Registration date
2020-11-15, 1399/08/25

Registrant information
Name
Hadi Vaezi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-21, 1399/09/01
Expected recruitment end date
2021-03-19, 1399/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effect of early vitrectomy on visual acuity of patients with endophthalmitis

Public title
Early vitrectomy for the treatment of endophthalmitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Endophthalmitis after the cataract surgery
Exclusion criteria:
patients who receive intra-viterous antibiotic injection
Age
No age limit
Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **24**
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 Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-10-24, 1399/08/03
Ethics committee reference number
IR.MUI.MED.REC.1399.648

Health conditions studied

1

Description of health condition studied
Endophthalmitis
ICD-10 code
H44.0
ICD-10 code description
Purulent endophthalmitis

Primary outcomes

1

Description
Visual acuity
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Snellen chart

2

Description
Retinal detachment
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Physical exam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in this group undergo early vitrectomy. This is done by washing the front room. A deep vitrectomy will then be performed. Depending on the condition of the retina, silicone oil will be injected and the periphery of retina will be checked at the end. Antibiotics will be injected into the vitreous and, if necessary, the trocar site will be sutured.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz hospital
Full name of responsible person
Farhad Fazel
Street address
Modares St., Ghods Sq.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hadi Vaezi
Position
Resident
Latest degree
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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