

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 4845

Email address

mhadivaezi@gmail.com

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-vitreous 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

Isfahan

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.

City

Isfahan

Province

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Postal code

8149644874

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+98 31 3445 2034

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fazel43@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Phone

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research@mui.ac.ir

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

Specialist

Other areas of specialty/work

Ophthalmology

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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