

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of efficacy of early vitrectomy and vitreous tap and injection in patients referring to Farabi Eye Hospital with diagnosis of post cataract surgery acute endophthalmitis and visual acuity of hand motion

#### Protocol summary

##### Study aim

Comparison of efficacy of early vitrectomy and vitreous tap and injection in patients referring to Farabi Eye Hospital with diagnosis of post cataract surgery acute endophthalmitis and visual acuity of hand motion

##### Design

Non randomized clinical trial , parallel arm groups, non randomized, 65 cases

##### Settings and conduct

Patient referring to Farabi eye Hospital with diagnosis of post cataract surgery endophthalmitis goes under vitrectomy

##### Participants/Inclusion and exclusion criteria

Patient with diagnosis of post cataract surgery endophthalmitis

##### Intervention groups

One group goes under early vitrectomy; another one goes under intravitreal antibiotic injection

##### Main outcome variables

Visual acuity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200115046148N1**

Registration date: **2020-02-10, 1398/11/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-02-10, 1398/11/21**

Update count: **0**

##### Registration date

2020-02-10, 1398/11/21

##### Registrant information

Name

soran aminzade

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 44 4244 4148

**Email address**

s-aminzade@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-01-29, 1398/11/09

**Expected recruitment end date**

2021-01-28, 1399/11/09

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of efficacy of early vitrectomy and vitreous tap and injection in patients referring to Farabi Eye Hospital with diagnosis of post cataract surgery acute endophthalmitis and visual acuity of hand motion

**Public title**

Comparison of efficacy of early vitrectomy and vitreous tap and injection in patients referring to Farabi Eye Hospital with diagnosis of post cataract surgery acute endophthalmitis and visual acuity of hand motion

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Post cataract surgery endophthalmitis

**Exclusion criteria:**

Any condition or disorder which affect visual acuity like diabetic retinopathy , glaucoma , retinal disorder and etc

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 65

**Randomization (investigator's opinion)**

Not 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**

Research Ethics Committee Farabi Eye Hospital-  
Tehran University of Medical Sciences

**Street address**

Farabi hospital, Qazvin Square, South Kargar Ave.,  
Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

5913813111

**Approval date**

2019-02-12, 1397/11/23

**Ethics committee reference number**

IR.TUMS.FARABIH.REC.1398.006

**Health conditions studied****1****Description of health condition studied**

Post cataract surgery Endophthalmitis

**ICD-10 code**

H44.0

**ICD-10 code description**

Purulent endophthalmitis

**Primary outcomes****1****Description**

Visual acuity

**Timepoint**

1 , 3 ,6 months afetr intervention

**Method of measurement**

Based on snelen chart and LogMAR

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: early vitrectomy; patients of this group who selected according to condition formerly explained will go on vitrectomy without any intervention priorly. Vitrectomy will be done through pars plana with small gauge needles and pus in the vitreous will be extracted by the way.

**Category**

Treatment - Surgery

**2****Description**

Control group: Intravitreal antibiotic injection; Vancomycin 1mg / 0.1 ml and ceftazidime 2.25 mg / 0.1 ml . The injection will be done and if the condition deteriorates during serial visits , the patient will go on delayed vitrectomy.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Farabi Hospital

**Full name of responsible person**

Soran Aminzade

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Qazvin Square , S kargar Ave , Tehran

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**Email**

soranaminzade90@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shokufeh Nikfar

**Street address**

Qazvin Square , S kargar Ave , Tehran

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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**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Soran Aminzade

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Data related to visual acuity and complications of surgery can be shared

**When the data will become available and for how long**  
After study ends up  
**To whom data/document is available**  
No limitation  
**Under which criteria data/document could be used**  
No limitation  
**From where data/document is obtainable**  
soranaminzade90@gmail.com  
**What processes are involved for a request to access data/document**  
After an email request, data will be sent as soon as possible  
**Comments**