

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### comparison of trabeculectomy with releasable sutures and standard trabeculectomy in treatment of glaucoma

#### Protocol summary

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##### Summary

The aim of this study to compare trabeculectomy with releasable sutures and standard trabeculectomy in treatment of glaucoma. Plan: A block-randomized, single-blind, placebo-controlled Clinical Trial, Phase II. Inclusion criteria: Primary open angle glaucoma, primary angle closure glaucoma who didn't respond to medication. Exclusion criteria: uveitis, post-traumatic, neovascular and Juvenile glaucoma. Previous ophthalmic surgery and combined procedures (glaucoma and cataract). Interventions: First group of patients will undergo a trabeculectomy with releasable sutures, and the second group will undergo a standard trabeculectomy. Primary outcome: Reduction in intraocular pressure.

##### Recruitment status

**Recruitment complete**

##### Funding source

research adjutancy of the arak university of medical sciences

##### Expected recruitment start date

2011-12-31, 1390/10/10

##### Expected recruitment end date

2012-11-30, 1391/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201401148410N2**

Registration date: **2014-09-10, 1393/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-09-10, 1393/06/19

##### Registrant information

###### Name

Ahmad Sarvarian

###### Name of organization / entity

Arak University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1313 5075

###### Email address

##### Scientific title

comparison of trabeculectomy with releasable sutures and standard trabeculectomy in treatment of glaucoma

##### Public title

trabeculectomy with releasable sutures in treatment of glaucoma

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: Primary open angle glaucoma; primary angle closure glaucoma who didn't Respond to medication exclusion criteria: uveitic; post-traumatic; neovascular; Juvenile glaucoma; Previous ophthalmic surgery; combined procedures (glaucoma and cataract)

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

### Sample size

Target sample size: 28

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of the arak university of medical sciences

##### Street address

Arak University of Medical Sciences, Alamolhoda Ave

##### City

Arak

##### Postal code

#### Approval date

2012-01-30, 1390/11/10

#### Ethics committee reference number

90-119-4

## Health conditions studied

### 1

#### Description of health condition studied

Glaucoma

#### ICD-10 code

H40.1

#### ICD-10 code description

Primary open-angle glaucoma

## Primary outcomes

### 1

#### Description

intraocular pressure

#### Timepoint

before trabeculectomy and 24 hours after trabeculectomy

#### Method of measurement

Goldmann tonometry

## Secondary outcomes

### 1

#### Description

shallow anterior chamber

#### Timepoint

24 hours after trabeculectomy

#### Method of measurement

measurement with slit lamp

### 2

#### Description

iridocorneal touch

#### Timepoint

24 hours after trabeculectomy

#### Method of measurement

observation with slit lamp

### 3

#### Description

corneal edema

#### Timepoint

24 hours after trabeculectomy

#### Method of measurement

observation with slit lamp

### 4

#### Description

Hyphema

#### Timepoint

24 hours after trabeculectomy

#### Method of measurement

observation with slit lamp

## Intervention groups

### 1

#### Description

patients of first group undergo trabeculectomy with releasable sutures. 24 hour after surgery anterior chamber depth, intraocular pressure, hyphema and iridocorneal touch will evaluate.

#### Category

Treatment - Surgery

### 2

#### Description

patients of second group undergo standard trabeculectomy. 24 hour after surgery anterior chamber depth, intraocular pressure, hyphema and iridocorneal touch will evaluate.

#### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Amirkabir Hospital

**Full name of responsible person**

Dr Ahmad Sarvarian

**Street address**

**City**

Arak

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Arak University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Dr Saeed Changizi Ashtiani

**Street address**

Arak University Of Medical Sciences, Basij Square

**City**

Arak

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak University of Medical Sciences, Vice chancellor for research

**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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Ahmad Sarvarian

**Position**

Ophthalmologist, Assistant Professor

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*