

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of Mitomycin C in intra-operative and post-operative in recurrent, visual acuity and intraocular pressure after pterygium surgery

#### Protocol summary

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##### Summary

Study design: randomized, single blind clinical trial. The purpose of this study was to compare recurrent, visual acuity and intraocular pressure after pterygium surgery using mitomycin C during and after surgery. In this interventional study, 120 patients with indications for pterygium surgery were enrolled and randomly divided into two groups. In first group, intraoperative mitomycin C 2% to 3 min and in second group, mitomycin C 2%, four times daily for 2 weeks was used and patients were followed up to 15 months after surgery. Collected data were analyzed by using SPSS software (version 16), Repeated measurement test at a significance level of 0.05.

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2010-08-23, 1389/06/01

##### Expected recruitment end date

2011-09-06, 1390/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207037466N3**

Registration date: **2014-06-07, 1393/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-07, 1393/03/17

##### Registrant information

###### Name

Reza Rezaei

###### Name of organization / entity

Ophthalmologist

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 239 1814

###### Email address

##### Scientific title

Effect of Mitomycin C in intra-operative and post-operative in recurrent, visual acuity and intraocular pressure after pterygium surgery

##### Public title

Effect of Mitomycin C in intra-operative and post-operative in recurrent, visual acuity and intraocular pressure after pterygium surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: signed informed consult, indication for pterygium surgery. exclusion criteria: dry eyes, history of vasculitis and collagen vascular diseases.

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

*No information*

## Sample size

Target sample size: 120

## 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

Arak university of medical sciences

##### Street address

Arak university of medical sciences, Arak, Iran

##### City

Arak

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

472

## Health conditions studied

### 1

#### Description of health condition studied

Pterygium

#### ICD-10 code

H11.0

#### ICD-10 code description

Pterygium

## Primary outcomes

### 1

#### Description

Recurrence

#### Timepoint

1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, 12 months and 15 months after intervention

#### Method of measurement

Clinical evaluation

## Secondary outcomes

### 1

#### Description

Intraocular pressure

#### Timepoint

1 day, 1 week, 2 weeks, 1 month, 3 months, 6 months, 9 months, 12 months and 15 months after intervention

#### Method of measurement

Tonometer application

## Intervention groups

### 1

#### Description

In first group, intraoperative mitomycin C 2% to 3 min and in second group, mitomycin C 2%, four times daily for 2 weeks was used and patients were followed up to 15 months after surgery.

#### Category

Treatment - Drugs

### 2

#### Description

mitomycin C 2%, four times daily for 2 weeks

#### Category

Treatment - Drugs

### 3

#### Description

intraoperative mitomycin C 2% to 3 min

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Kabir Hospital

##### Full name of responsible person

Dr Reza rezaei

##### Street address

Department of ophthalmology, Amir Kabir Hospital, Shiroudy Street, Alamol Hoda Street, Arak, Markazi Province, I. R. Iran

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences, Deputy of Education and research

##### Full name of responsible person

Dr Davood Hekmatpou

**Street address**

Deputy of Education ad research, Arak university of medical sciences, Basij Sq., Arak, Iran

**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, Deputy of Education ad research

**Proportion provided by this source****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

**2****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Shabestari

**Street address**

Arak, Iran

**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

**Proportion provided by this source****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 Reza Rezaei

**Position**

Assistant prof.

**Other areas of specialty/work****Street address**

Department of ophtalmology, Amir Kabir hospital, Alamolhoda St., Shiroudy St., Arak, Iran

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+98 86 3313 2510

**Email****Web page address**

## **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*