

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 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

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Position

Assistant prof.

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

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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