Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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.

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
Ophtalmologist
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Iran (Islamic Republic of)
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dr.rezarezaei@arakmu.ac.ir

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

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 ad 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

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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