Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

: The effect of usage combination of Betadine 10%drop/ Levofloxacin drop the number of conjunctival bacterial colony culture preparation during cataract surgery

Protocol summary

Study aim

Determine effect of usage combination of betadine 10%drop/ levofloxacin drop before surgery on the number of conjunctival bacterial colony culture preparation during cataract surgery in Khalili Hospital affiliated to shiraz University of Medical Sciences

Design

clinical trail inclusive control group، group parallel، double blind- randomization

Settings and conduct

This randomized clinical trial will be performed in Khalili hospital, Shiraz, . After transferring the patients to the operating room, the first culture will be taken from the inferior conjunctival fornix using a swab. Then, the patients will be divided into two groups randomly. The first group will receive tetracaine drops, while the second group will receive tetracaine, betadine 10%, and levofloxacin drops. After general anesthesia, the second culture will be obtained from the inferior conjunctival fornix using a swab. All patients will receive betadine 10% drops and after three minutes, the third culture will be taken from the inferior conjunctival fornix using a swab. the fourth culture will be taken from the inferior conjunctival fornix using a swab at the end of the surgery.

Participants/Inclusion and exclusion criteria

inclusion criteria : Being scheduled for cataract surgery, not suffering from serious kidney diseases, not having infections in other body organs, aging above 50 years, not having consumed topical or systemic antibiotics over 10 days prior to the operation, being willing to take part in the research. Exclusion criteria :Suffering from diabetes and rheumatoid arthritis,having infections

Intervention groups

intervention groups :This group will receive tetracaine, betadine 10%, and levofloxacin drops. control groups:This group will only receive tetracaine and betadine drops.

Main outcome variables

The number of conjunctival normal flora bacterial colony

General information

Reason for update

Acronym

B and L

IRCT registration information

IRCT registration number: **IRCT20190212042693N1**
Registration date: **2019-07-24, 1398/05/02**
Registration timing: **retrospective**

Last update: **2019-07-24, 1398/05/02**
Update count: **0**

Registration date

2019-07-24, 1398/05/02

Registrant information

Name

roghayeh rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3821 4644

Email address

rezaeero@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-26, 1397/11/06

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: The effect of usage combination of Betadine 10%drop/ Levofloxacin drop the number of conjunctival bacterial colony culture preparation during cataract surgery

Public title

The effect of usage combination of Betadine 10%drop/ Levofloxacin drop the number of conjunctival bacterial colony culture preparation during cataract surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being scheduled for cataract surgery not suffering from serious kidney diseases not having infections in other body organs aging above 50 years not having consumed topical or systemic antibiotics over 10 days prior to the operation and being willing to take part in the research.

Exclusion criteria:

Suffering from diabetes disease Rheumatoid Arthritis having infection

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

premunted block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study all participates have not any information about kind of drop and also laboratory personnel have not any information about specimens

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Ave: Shiraz univercity Medical Science

City

shiraz

Province

Fars

Postal code

713451978

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.SUMS.REC.1398.011

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25

ICD-10 code description

Age-related cataract

2

Description of health condition studied

Endophthalmitis

ICD-10 code

H44.1

ICD-10 code description

Other endophthalmitis

Primary outcomes

1

Description

The number of conjunctival normal flora bacterial colony

Timepoint

before intervention -after intervention-after than 3 minute- end of surgery

Method of measurement

growth bacteria under media blood

Secondary outcomes

empty

Intervention groups

1

Description

Intervention groups:This group will receive tetracaine, betadine 10%, and levofloxacin drops.drops produces

Finland .drops will obtains after enter patients into operating room

Category

Prevention

2

Description

Control groups: This group will only receive tetracaine and betadine drops. drops produces Iran

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili hospital

Full name of responsible person

Roghayeh rezaee

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Kalili Ave: Khalili hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

jamshid Eslami

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yarden@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

roghayeh rezaee

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Postal code

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available