

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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 trial 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

**Street address**

Kalili Ave: Khalili hospital

**City**

Shiraz

**Province**

Fars

**Postal code**

713451978

**Phone**

+98 71 3629 1833

**Email**

rezaeero@sums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

jamshid Eslami

**Street address**

zand Ave: Shiraz University of Medical Science

**City**

Shiraz

**Province**

Fars

**Postal code**

713451978

**Phone**

+98 71 3230 5413

**Email**

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

**Street address**

Khalili Ave :Khalili hospital

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**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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student

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**Person responsible for updating data**

**Contact**

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student

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**Postal code**

713451978

**Phone**

+98 71 3629 1833

**Email**

rezaeero@sums.a1438845276c.ir

**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