

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of Povidon-iodine Concentration Intervention on ophthalmic Surgeries Sterilization: Randomized Clinical Trial

#### Protocol summary

##### Study aim

To find out which concentrations of povidone-iodine are effective in sterilizing ophthalmic operations, based on the lowest possible concentration

##### Design

Parallel clinical trial design was employed to achieve aforementioned objectives. 60 patients will be assigned to join the study group

##### Settings and conduct

60 patients undergoing to ophthalmic surgery who were admitted to Ibn Al-Haitham eye teaching hospital at Baghdad city . On-randomized probability sample

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients undergoing to ophthalmic surgery, male and female and all ages , exclusions criteria:patient refused

##### Intervention groups

The start point of intervention phase will start by applying povidon iodine on the eye fore 3 minutes before surgery and take swab from eyelid , eyelashes and conjunctiva and send to culturing.

##### Main outcome variables

The sterilization will occur with this concentration of povidon-iodine

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211022052840N2**

Registration date: **2023-07-13, 1402/04/22**

Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**

Update count: **0**

##### Registration date

2023-07-13, 1402/04/22

#### Registrant information

##### Name

Omar AL-Ghrai

##### Name of organization / entity

University of Baghdad, College of Nursing

##### Country

Iraq

##### Phone

+964 1 521 1495

##### Email address

omar.thamer1202a@conursing.uobaghdad.edu.iq

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-11-21, 1403/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Efficacy of Povidon-iodine Concentration Intervention on ophthalmic Surgeries Sterilization: Randomized Clinical Trial

#### Public title

Povidon-iodine Preparation Intervention on ophthalmic Surgeries Sterilization

#### Purpose

Screening

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

All ocular surgeries

##### Exclusion criteria:

Patient refused

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple random sample that includes applying povidone-iodine in different concentrations before ophthalmic surgeries, where a concentration of 10% is applied, and then we take a swab from the eyelid and eyelashes conjunctiva. In the second group, the experiment is conducted by applying sterilization at a concentration of 5%, and swabs are taken from the eyelids, eyelashes, and eye conjunctiva. In the third group, a concentration of 2.5% is applied and swabs are taken from the eyelids, eyelashes, and eye conjunctiva. These swabs are sent to the laboratory for the purpose of cultivation and examination of whether bacterial growth has occurred.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Double blind: the participants, investigators or the assessors of the outcomes unaware of the intervention

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

No one

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethical Approval Committee' at the college of nursing

**Street address**

Bab-AL-Muaadham Street

**City**

Baghdad

**Postal code**

10001

**Approval date**

2066-03-11, 1444/12/21

**Ethics committee reference number**

3756

**Health conditions studied****1****Description of health condition studied**

Sterilization of ocular surgeries by applying povidone iodine in different concentrations

**ICD-10 code**

Z30.2

**ICD-10 code description**

Encounter for sterilization

**Primary outcomes****1****Description**

Sterilization with less concentrations of povidone iodine to minimize toxicity and no contamination occurs

**Timepoint**

At same time of surgery

**Method of measurement**

Swab and culture at laboratory to see if any bacterial growth

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: applying three concentrations of povidone iodine to sterilize eye before surgery first group with 2.5% the second one 5% and the third group 10% for 3min and take Swab and culture to see bacterial growth and the inner of eye sterilization with low concentrations 2.5 and 5% for 1min trial will include 60 patients (random sample sampling)

**Category**

Treatment - Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ibn-AL-Hathim eye Teaching Hospital

**Full name of responsible person**

Waleed H. Jasm senior doctor ophthalmologist

**Street address**

Al anduls

**City**

Baghdad

**Postal code**  
10001  
**Phone**  
+964 782 695 6615  
**Email**  
omar.thamer1202a@conursing.uobaghdad.edu.iq  
**Web page address**  
<https://www.medicalcity.gov.iq/ar/contact-us>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
College of Nursing, Baghdad university  
**Full name of responsible person**  
Professor wasaam Jabar ,PhD, Dean  
**Street address**  
Bab AL-Muaadam Campus  
**City**  
Baghdad  
**Postal code**  
10001  
**Phone**  
+964 782 695 6615  
**Email**  
omar.thamer1202a@conursing.uobaghdad.edu.iq  
**Web page address**  
<https://www.medicalcity.gov.iq/ar/contact-us>

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

The author of the trial is the funding source

#### 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**  
College of nursing Baghdad university  
**Full name of responsible person**  
Omar Tamer Ghrairi  
**Position**  
Nursing specialist  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Ophthalmology

#### Street address

Yarmuk

#### City

Baghdad

#### Province

Baghdad

#### Postal code

10001

#### Phone

+964 782 695 6615

#### Email

omar.thamer1202a@conursing.uobaghdad.edu.iq

#### Web page address

<https://www.medicalcity.gov.iq/ar/contact-us>

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
College of Nursing, Baghdad university  
**Full name of responsible person**  
Omar Ghrairi  
**Position**  
Surgical assistant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Ophthalmology  
**Street address**  
Yurmouk  
**City**  
Baghdad  
**Province**  
Baghdad  
**Postal code**  
10001  
**Phone**  
+9648826956615  
**Email**  
omar.thamer1202a@conursing.uobaghdad.edu.iq  
**Web page address**  
<https://www.medicalcity.gov.iq/ar/contact-us>

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Nursing College, Baghdad university  
**Full name of responsible person**  
Omar Ghrairi  
**Position**  
Surgical assistant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Ophthalmology  
**Street address**  
Yurmok  
**City**  
Baghdad  
**Province**

Baghdad  
**Postal code**  
10001  
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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

Yes - There is 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**

Not applicable

### **Analytic Code**

Not applicable

### **Data Dictionary**

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

### **Title and more details about the data/document**

The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals

### **When the data will become available and for how long**

God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications

### **To whom data/document is available**

All the related files will be shared with any scientific interested parties.

### **Under which criteria data/document could be used**

It may be used after seeking the author's permission and acknowledging his contribution.

### **From where data/document is obtainable**

The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail:

Omar.thamer1202a@conursing.uobaghdad.edu.iq

### **What processes are involved for a request to access data/document**

N/V

### **Comments**

Appreciation and thanks to IRCT members for their efforts in supporting researchers