ISRCTN13265494 https://doi.org/10.1186/ISRCTN13265494

A clinical trial to evaluate the safety and effectiveness of the corneo-capsular protection system (CCPS - Shamil Device) in protecting the eye during cataract surgery

Submission date
10/10/2024

Recruitment status
No longer recruiting

Registration date
11/10/2024

Overall study status
Completed

Last Edited
11/10/2024

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cataracts are a common condition where the clear lens of the eye becomes cloudy, causing blurred vision and, if left untreated, can lead to blindness. The standard treatment for cataracts is surgery, where the cloudy lens is removed and replaced with an artificial lens. While cataract surgery is generally very safe, there are risks involved, especially potential damage to parts of the eye, such as the corneal endothelium (the inner layer of the cornea) and the posterior capsule (the membrane that holds the lens in place).

This study aims to evaluate the safety and effectiveness of a new device called the Corneo-Capsular Protection System (CCPS) "Shamil Device". This device is designed to protect the eye's sensitive structures during cataract surgery, reducing the risk of complications and improving patient outcomes. By providing additional protection, we hope the CCPS will make cataract surgery even safer.

Who can participate?
Adults aged 50 years or older who are scheduled for cataract surgery can participate in this study. To be eligible, participants should be in generally good health and willing to attend follow-up appointments after surgery. People who have had previous eye surgeries, certain eye conditions, or significant health issues such as uncontrolled diabetes will not be able to participate.

What does the study involve?
Participants will be randomly divided into four groups:

One group will receive the CCPS device to protect both the cornea and posterior capsule during surgery.
Another group will receive the CCPS device to protect only the cornea.
A third group will receive the CCPS device to protect only the posterior capsule.

The final group will have standard cataract surgery without the use of the CCPS device.
All participants will have standard cataract surgery, but some will have the additional protection of the CCPS device, which is made from materials commonly used in eye surgeries. After the surgery, participants will be monitored to assess their recovery and any complications. Follow-up visits will be scheduled at 1 day, 1 week, 1 month, and 2 months after the surgery.

What are the possible benefits and risks of participating?
The potential benefit for participants is the added protection provided by the CCPS device, which may reduce the risk of damage to the cornea or posterior capsule during surgery. This could lead to faster recovery and better vision outcomes after surgery. Even for those in the standard surgery group, the knowledge gained from this study could help improve cataract surgeries for future patients.

As with all surgeries, there are some risks, such as infection, inflammation, or temporary increases in eye pressure. However, the CCPS device is made from safe, biocompatible materials already used in similar eye procedures, so we do not expect it to introduce additional risks. Any complications will be managed according to standard medical practice.

Where is the study run from?
The study will be conducted at multiple medical centers in Morocco, including:
Hôpital Oued Eddahab, Agadir
Clinique Tifaout, Agadir
Centre Nadar, Rabat
Ophtalmoclinic Noor, Casablanca

When is the study starting and how long is it expected to run for?
January 2024 to January 2025

Who Is Funding the Study?
This study is funded by the Laboratory of Medical-Surgical Research, Biotechnology, and Infectious Diseases (BIOMCI), part of the Faculty of Medicine and Pharmacy of Agadir, affiliated with Ibnou Zohr University (Morocco)

Who Is the Main Contact?
Dr Louaya Shamil, louayashamil@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Shamil Louaya

ORCID ID
https://orcid.org/0000-0003-2838-1119

Contact details
cité rizk
Agadir
Morocco

80100
+212 661086320
z.lemkhente@uiz.ac.ma

Additional identifiers

Protocol serial number
19081976

Study information

Scientific Title
A randomized, double-blind clinical trial evaluating the efficacy and safety of the the corneo-capsular protection system (CCPS - Shamil Device) compared to standard care in cataract surgery, with primary outcomes of corneal endothelial protection and posterior capsule integrity

Acronym
CCPS - Shamil Device

Study objectives
1. The CCPS (Corneo-Capsular Protection System) – Shamil Device provides better protection for the corneal endothelium during cataract surgery compared to standard surgical methods.
2. The CCPS – Shamil Device reduces the incidence of posterior capsule rupture in cataract surgery compared to traditional techniques.

Ethics approval required
Ethics approval not required

Ethics approval(s)
This trial does not require ethics committee approval as the CCPS (Corneo-Capsular Protection System) uses biocompatible materials similar to those found in existing intraocular implants, which are routinely used in standard cataract surgeries. These materials have been thoroughly tested for safety and efficacy.

Primary study design
Interventional

Study design
Multicentre randomized double-blind controlled interventional trial with parallel assignment

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Intraocular protection and prevention of surgical complications in cataract surgery by using the CCPS (Corneo-Capsular Protection System) "Shamil Device".

Interventions
Randomisation:
- Participants will be randomly allocated to one of the four groups (TPG, CDOG, CFOG, or CG).

- A sealed envelope method will be used to ensure randomization.
- The study will be conducted as a double-blind trial, where both participants and outcome assessors will be unaware of the group allocations.

1. Total Protection Group (TPG):
- Both the corneal protection dome (0.3 mm) and the capsular protection floor (0.2 mm) will be used during cataract surgery.
- The corneal protection dome is positioned under the corneal endothelium, and the capsular floor is inserted in the sulcus under the crystalline nucleus to protect the posterior capsule.
- Both components are inserted before phacoemulsification. The capsular protection floor is removed before lens implantation, while the corneal protection dome is removed after the lens is implanted.

2. Corneal Dome Only Group (CDOG):
- Only the corneal protection dome will be inserted under the endothelium.
- It will be used during phacoemulsification and removed after the lens is implanted.

3. Capsular Floor Only Group (CFOG):
- Only the capsular protection floor will be placed in the sulcus under the crystalline nucleus.
- It will be used during phacoemulsification and removed before lens implantation.

4. Control Group (CG):
- Standard cataract surgery using phacoemulsification without the use of any protective device (no dome or floor).

Follow-Up Schedule:
- Participants will be evaluated post-operatively at Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60).
- The evaluations will focus on:

Clinical Evaluation:
- Slit-lamp examination to assess corneal transparency, signs of inflammation, and any complications.

Evaluation of Complications Related to Posterior Capsule Damage:
- Posterior capsule rupture: Assessed via intraoperative and postoperative monitoring to detect any signs of posterior capsule breakage.
- Vitreous prolapse: Monitoring for any presence of vitreous prolapse into the anterior chamber, a common complication of posterior capsule rupture.
- Intraocular lens dislocation: Assessing the correct positioning and stability of the intraocular lens (IOL) postoperatively.
- Posterior capsule opacification (PCO): Monitoring the development of any opacification of the posterior capsule, which can impact vision and may require YAG laser capsulotomy.

Evaluation of Complications Related to the Corneal Endothelium:
- Visual improvement.

Specular Microscopy:
- Used to evaluate the health and density of corneal endothelial cells, specifically measuring endothelial cell loss and morphology over time.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The CCPS (Corneo-Capsular Protection System) "Shamil Device".

Primary outcome(s)
1. Corneal endothelial cell density is measured using specular microscopy at baseline (pre-surgery), Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery
2. Status of the posterior capsule and anterior chamber is assessed via slit-lamp biomicroscopy at the same time points: Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery

Key secondary outcome(s)
1. Visual acuity measured using a Snellen chart at baseline, Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery
2. Intraocular pressure (IOP) measured using a tonometer at baseline, Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery
3. Incidence of posterior capsule opacification (PCO) assessed via slit-lamp biomicroscopy at Day 30 (J+30) and Day 60 (J+60) post-surgery
4. Postoperative complications, such as inflammation, assessed via slit-lamp biomicroscopy at Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery
5. Corneal edema and corneal thickness measured using slit-lamp biomicroscopy and pachymetry at Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Adults aged 50 years or older undergoing cataract surgery
2. Diagnosed with age-related cataract requiring surgical intervention
3. Good general health, with no severe systemic illnesses that could affect surgical outcomes
4. Able to provide informed consent
5. Willing and able to attend follow-up appointments at Day 1 (J+1), Day 8 (J+8), Day 30 (J+30), and Day 60 (J+60) post-surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Key exclusion criteria
1. History of previous intraocular surgery or trauma in the eye undergoing cataract surgery
2. Presence of any corneal disease that could interfere with the outcome of surgery
3. Uncontrolled glaucoma or other severe ocular conditions that may affect the surgical results
4. Allergy or hypersensitivity to materials used in the intraocular lens or surgical instruments
5. Pregnancy or breastfeeding
6. Inability to provide informed consent or comply with the follow-up schedule
7. Significant systemic diseases (e.g., uncontrolled diabetes or cardiovascular disease) that could interfere with recovery or increase surgical risk

Date of first enrolment
01/09/2024

Date of final enrolment
01/11/2024

Locations

Countries of recruitment
Morocco

Study participating centre
HMOED
Pergola
Agadir
Morocco
80100

Study participating centre
Tifaout ophtalmology clinic
talborjet
Agadir
Morocco
80100

Study participating centre
Centre Nadar
103 Av. Sidi Mohamed Ben Abdellah

Rabat
Morocco
10100

Study participating centre
Ophtalmoclinic Noor
10 Av. des Nations Unies
Rabat
Morocco
10090

Sponsor information

Organisation
Laboratory of Medical-Surgical Research, Biotechnology, and Infectious Diseases (BIOMCI)

Funder(s)

Funder type
University/education

Funder Name
Laboratory of Medical-Surgical Research, Biotechnology, and Infectious Diseases (BIOMCI)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be available upon reasonable request from researchers for the purpose of scientific analysis.
Requests for data should be directed to Dr. Louaya Shamil (email: louayashamil@gmail.com).
The data will be anonymized to ensure participant confidentiality, with all personal identifiers removed.
Type of data to be shared: Individual participant-level data, including outcome measures such as corneal endothelial cell counts, intraocular pressure measurements, and visual acuity scores.
When available: Data will be made available 6 months after publication of the study results.
How long: The data will be available for 5 years from the time of first publication.
Access criteria: Data will be shared with researchers who provide a scientific rationale for data use and agree to sign a data-sharing agreement ensuring compliance with ethical and legal standards.
Consent: Participant consent was obtained for sharing anonymized data for research purposes.

Mechanism: Data will be shared via email in a secure format, or uploaded to a secure data repository upon request.
Ethical/legal restrictions: All data sharing will be subject to ethical review to ensure that the use of data aligns with the original study's ethics approval and conforms to data protection laws.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes