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Research on the application of low-temperature perfusion in different cataract surgeries

Submission date
30/11/2025

Recruitment status
No longer recruiting

Registration date
10/12/2025

Overall study status
Ongoing

Last Edited
09/12/2025

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Currently, cataract is the leading cause of blindness worldwide. Ultrasound aspiration cataract extraction surgery and small incision cataract removal surgery have gradually been accepted by ophthalmologists and patients due to their advantages, such as small incisions, minimal tissue damage, less postoperative astigmatism, and rapid visual function recovery. These surgeries have been widely used in clinical practice. However, during the operation, ultrasonic energy and surgical procedures may cause postoperative corneal edema, anterior chamber inflammation, and even corneal endothelial dysfunction. They can also lead to an increase in the thickness of the macular fovea retinal layer and macular edema, significantly affecting the recovery of patients' postoperative vision. Previous studies have shown that low temperature is a protective factor, enhancing the body's tolerance to ischemia and hypoxia. Since lowering the temperature can reduce tissue metabolism, low-temperature therapy is used to treat heart and brain injuries. In the eye, studies have shown that low-temperature perfusion has a protective effect on corneal endothelial cells during ultrasound aspiration surgery. In experiments on internal eye posterior segment surgery, creating a local low-temperature environment through intraocular perfusion fluid effectively protects the blood-retinal barrier, and the tolerance of certain functional retinal cells to hypoxia and damage is also enhanced. This study investigates the effect of low-temperature perfusion during cataract extraction surgery on the blood-retinal barrier by monitoring changes in macular fovea retinal layer thickness before and after the operation, as well as postoperative best-corrected visual acuity, intraocular pressure, and corneal endothelial cell count. This study establishes a simple and cost-effective method for local low-temperature treatment, which is convenient to implement.

Who can participate?
Patients aged 60 to 80 who have been diagnosed with senile cataracts, lens nucleus hardness grade III (Emery grading system), corrected visual acuity below 0.4, refractive error ≤ ± 6.0D, and the ability to fixate with both eyes.

What does the study involve?
The patients meeting the requirements will be divided into four groups. Group 1: Low-temperature phacoemulsification group; Group 2: Low-temperature small incision group; Group 3: Normal-temperature phacoemulsification group; Group 4: Normal-temperature small incision

group. During the operation, the low-temperature group was given 4 degrees Celsius perfusion fluid, while the normal-temperature group was given 24 degrees Celsius (room temperature) perfusion fluid. The intraoperative eye temperatures, preoperative and postoperative corrected visual acuity, intraocular pressure, corneal endothelial cell count, and macular foveal retinal thickness of these four groups of patients were observed. Data were collected separately on the day before the operation, one day after the operation, one week after the operation, one month after the operation, and three months after the operation.

What are the possible benefits and risks of participating?
The research participants will benefit from the strict follow-up. Any postoperative complications, including high intraocular pressure or corneal edema, will be diagnosed and treated promptly. Most importantly, the establishment of a local hypothermia method during cataract surgery is simple, cost-effective, and easy to implement. Adding an extra protective measure during the surgery will be highly beneficial. The control group will also adopt the conventional surgical method and will not incur additional risks.

Where is the study run from?
The Ophthalmology Department of Nanjing Central Hospital, China.

When is the study starting and how long is it expected to run for?
March 2024 to December 2024.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr. Xi Meng, mengxi19882025@163.com

Contact information

Type(s)
Scientific, Principal investigator, Public

Contact name
Mrs Xi Meng

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Additional identifiers

Study information

Scientific Title

A randomized controlled trial evaluating the safety and efficacy of low-temperature versus normothermic irrigating solutions in patients undergoing various types of cataract surgery

Acronym
TEMP-CAT

Study objectives
Cataracts are the leading cause of reversible blindness and visual impairment worldwide. This study aimed to investigate the safety and efficacy of hypothermic perfusion in cataract patients undergoing various types of cataract surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/02/2024, Medical Ethics Committee of Nanjing Central Hospital (Nanjing Central Hospital, 116 Chengxian Street, Xuanwu District, Nanjing, Jiangsu Province, 210008, China; +86-025-68781517; zxyykjk517@126.com), ref: 202406

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Diagnostic

Study type(s)

Health condition(s) or problem(s) studied
Effect of hypothermic perfusion on in different cataract surgeries.

Interventions
All patients will be divided into two groups based on different surgical methods: the phacoemulsification cataract extraction group (Group A) and the small incision extracapsular cataract extraction group (Group B). Subsequently, patients in each group will be randomly assigned using a random number table to either the hypothermia group (using a 4 intraocular perfusion solution) or the normothermia group (using a 22 intraocular perfusion solution) prior to surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Intraoperative corneal surface temperature measured using an infrared thermometer at before surgery, 1 day, 1 week, 1 month and 3 months after surgery

2. corneal endothelial cell density (ECD) measured using a corneal endothelial microscope at before surgery, 1 day, 1 week, 1 month and 3 months after surgery

Key secondary outcome(s))
1. Intraocular pressure (IOP) measured using a non-contact tonometer at before surgery, 1 day, 1 week, 1 month and 3 months after surgery

2. Central macular thickness (CMT) measured using optical coherence tomography (OCT) at before surgery, 1 day, 1 week, 1 month and 3 months after surgery

Completion date
25/12/2025

Eligibility

Key inclusion criteria
1. Diagnosed with senile cataracts
2. Lens nucleus hardness grade III (Emery grading system)
3. Corrected visual acuity below 0.4, refractive error ≤ ± 6.0D
4. Ability to fixate with both eyes
5. Completion of relevant examinations and availability of complete clinical and follow-up records

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
80 years

Sex
All

Total final enrolment
120

Key exclusion criteria

1. History of ocular trauma or ocular surgery
2. Presence of concomitant ocular diseases, such as corneal lesions, glaucoma, or age-related macular degeneration
3. Loss to follow-up or incomplete follow-up data

Date of first enrolment
12/03/2024

Date of final enrolment
25/12/2024

Locations

Countries of recruitment
China

Study participating centre
Nanjing Central Hospital
Ophthalmology Department, Nanjing Central Hospital, 116 Chengxian Street, Xuanwu District
Nanjing, Jiangsu Province
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210008

Sponsor information

Organisation
Nanjing Central Hospital

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from (Xi Meng, mengxi19882025@163.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	01/03/2024	09/12/2025	No	Yes