# Nanjing Central Hospital

## Participant Information Sheet

**1. Title of Study**

Research on the Application of Low-Temperature Perfusion in Different Cataract Surgeries

**2. Version Number and Date**

Version 1, March 1st, 2024.

**3. Invitation Paragraph**

You are invited to participate in a research study. Before you decide whether or not to participate, it is important for you to understand how this research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like to have more information. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

**4. What is the purpose of the study?**

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.

**5. Why have I been chosen to take part?**

We are currently seeking surgical patients aged between 60 and 80 who have senile cataracts to participate in this study. You meet our criteria, and therefore have been selected.

**6. Do I have to take part?**

Your participation is voluntary, and you are free to withdraw at any time without explanation and without incurring a disadvantage.

**7. What will happen if I take part?**

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.

**8. Expenses and / or payments**

There is no expense or payment for participating in this project.

**9. Are there any risks in taking part?**

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. The control group will also adopt the conventional surgical method and will not incur additional risks.

**10. Are there any benefits in taking part?**

The use of local hypothermia therapy in cataract surgery is simple, economical and easy to implement. Adding an additional protective measure during the surgery would be very beneficial.

**11. What if I am unhappy or if there is a problem?**

If you are unhappy, or if there is a problem, please feel free to let me know at mengxi19882025@163.com.

**13. What will happen if I want to stop taking part?**

Participants can withdraw at any time without explanation. Results up to the period of withdrawal may be used, if you are happy for this to be done. Otherwise you may request that they are destroyed and no further use is made of them.

**14. Who can I contact if I have further questions?**

The contact details of the lead researcher (principal investigator) is:

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