Official title： A prospective randomized controlled study on the safety and effectiveness of microscopic varicocele transposition surgery compared with simple ligation

NCT number：

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Informed Consent Form

Dear Sir,

We invite you to participate in a research project approved by the Ethics Committee of Sichuan Provincial People's Hospital: "A Prospective Randomized Controlled Study on the Safety and Efficacy of Microscopic Varicocele Revascularization Compared with Simple Ligation." This study is led by Chief Physician Dou Ke from the Urology Andrology Department and will be conducted in the Urology Andrology Department of Sichuan Provincial People's Hospital. Approximately 284 participants are expected to voluntarily join, with 284 subjects planned for enrollment at this center. The study has been reviewed and approved by the Basic and Clinical Research Ethics Committee of Sichuan Academy of Medical Sciences & Sichuan Provincial People's Hospital, with the ethics review number: .

Why is this study being conducted?
Varicocele is a common urogenital disease in males, with a high incidence in the male population, particularly among patients with primary male infertility. Varicocele can cause elevated local scrotal temperature and poor blood circulation, thereby affecting testicular spermatogenesis and endocrine function, leading to decreased semen quality and male infertility. Currently, microscopic varicocele revascularization and simple ligation are both common surgical methods for treating varicocele, but there is no clinical consensus on the efficacy and safety of these two procedures. Simple ligation is relatively easy to perform but may have issues such as postoperative recurrence and insignificant improvement in semen quality. In theory, microscopic varicocele revascularization can better preserve normal blood vessels and lymphatic vessels within the spermatic cord, reduce complications, and more effectively improve semen quality, but this procedure has a higher surgical difficulty and requires advanced technical skills from the surgeon. This study aims to conduct a prospective, randomized controlled trial to compare the efficacy of microscopic varicocele revascularization and simple ligation in treating varicocele. Specifically, it will compare postoperative semen quality improvement, varicocele recurrence rate, surgical success rate, complication rate, and other indicators between the two surgical methods, to determine whether microscopic varicocele revascularization has advantages over simple ligation, provide a scientific and reliable basis for clinicians to select more appropriate treatment options, and ultimately improve the treatment outcomes and quality of life for varicocele patients.

Who is suitable (or unsuitable) to participate in the study?
Inclusion Criteria:
1. Diagnosed with varicocele through clinical examinations (physical examination, ultrasound, etc.) and meeting the clinical diagnostic criteria for varicocele.
2. Male patients aged between 18 and 60 years.

3. Patients with treatment intention, willing to participate in this study and sign the informed consent form.
4. Semen analysis shows abnormalities, such as reduced sperm count, decreased motility, abnormal morphology, etc., which are related to varicocele.
5. No severe dysfunction of vital organs such as heart, lung, liver, and kidney, and able to tolerate surgery.
6. No relevant treatments affecting varicocele condition or semen quality in the past 3 months.

Exclusion Criteria:
1. Secondary varicocele (caused by other diseases such as retroperitoneal tumors, renal tumors, etc.).
2. Complicated with other severe reproductive system diseases, such as epididymitis, orchitis, testicular tumor, etc.
3. Suffering from severe systemic diseases, such as uncontrolled hypertension, diabetes, malignant tumors, etc., which may affect surgical outcomes or prognosis.
4. Coagulation dysfunction or taking medications affecting coagulation function.
5. Allergic history to medications used in surgery (such as anesthetics, etc.).
6. Mental illness or cognitive impairment, unable to cooperate with the completion of this study.
7. Already participating in other related clinical trials.

What will be required if you participate in the study? (Mainly to inform in detail the research methods, processes, steps, and precautions)
If you agree to participate in this study, during the screening period, we will conduct a detailed medical history interview and comprehensive physical examination, and you will undergo blood tests (sex hormone testing, blood routine, coagulation function, and liver/kidney function tests), Doppler ultrasound, semen routine analysis, etc. We will screen and assign groups based on the above results.

During the intervention period, you may receive one of the following two treatment plans: the experimental group will undergo microscopic varicocele revascularization, where the spermatic vein is ligated under a microscope, and 1-2 spermatic veins are drained into the inferior epigastric vein; the control group will undergo microscopic simple spermatic vein ligation, where only the spermatic vein is ligated under a microscope.

During the follow-up period, we will conduct semen tests, Doppler ultrasound, blood tests, etc., once at 4 weeks after treatment, and will follow up again at 24 weeks after treatment, conducting semen analysis, Doppler ultrasound, blood tests, etc., once more. Your participation in this study will take approximately six months.

What are the benefits of participating in the study?

By participating in this study, your varicocele may improve, and the study will help determine whether microscopic varicocele revascularization can more safely and effectively treat other patients with similar conditions.

What are the risks of participating in the study?
This study involves some risks, mainly related to surgery, including: (1) Anesthesia and cardiovascular and cerebrovascular accidents; (2) Intraoperative and postoperative bleeding; (3) Peripheral tissue injury; (4) Unimproved postoperative reproductive function or discomfort symptoms; (5) Postoperative recurrence; (6) Wound infection, poor healing, etc. The experimental group will decide the vascular anastomosis method based on intraoperative conditions. We will operate carefully, achieve meticulous hemostasis, strictly enforce aseptic techniques, and collaborate closely with anesthesiologists and nursing staff to minimize the occurrence of the above risks.

In addition, this study also has the following risks: research results may have biases such as selection bias, measurement bias, and loss to follow-up; ethically, there may be dilemmas if one procedure is significantly superior but the trial continues; psychologically, patients may experience anxiety, depression, or other psychological issues due to worries.

Will there be any costs to participate in the study?
Whether you are in the experimental group or the control group, the surgical methods used are conventional procedures, and varicocele will be effectively treated, so this study does not exempt hospitalization fees. To compensate for the inconvenience caused by your participation in this study, you can receive free follow-up consultations during the study's follow-up period.

Is personal information kept confidential?
Your medical records will be stored in the hospital, and researchers, research supervisory authorities, and the ethics committee will be permitted to access your medical records. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the scope permitted by law.

What are the alternative treatment options if you do not participate in the study?
If you do not participate in this study or withdraw midway, there are many alternative treatment options, such as drug therapy or direct surgical treatment.

Must you participate in the study?
Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time during the process, which will not affect the doctor's treatment of you. If you decide to withdraw from the study, please contact

your doctor, and you may be required to undergo relevant examinations, which is beneficial for protecting your health.

If you have any questions regarding your personal rights and interests, please contact the hospital's Ethics Committee at: 028-87393449.

Subject's Statement: I have read the above introduction to this study, fully understand the potential risks and benefits of participating in this study, and voluntarily agree to participate. I will receive a copy of this informed consent form signed and dated by both parties.

I agree □ or refuse □ to allow other research studies to use my medical records and clinical specimens related to this study.

Research Participant's Signature: _____ Date: _____ Year _____ Month _____ Day
Research Participant's Contact Telephone: _____ Mobile Phone: _____

(When applicable) Guardian/ Witness Signature: _____ Date: _____ Year _____ Month _____ Day
Guardian/ Witness Contact Telephone: _____ Mobile Phone: _____

Researcher's Statement: I confirm that I have explained the details of this study to the subject, particularly the potential risks and benefits of participating in the study, and have answered all the subject's questions. The subject has voluntarily agreed to participate in this study. This informed consent form is in duplicate, with one copy retained by the researcher and one by the subject.

Research Physician's Signature: _____ Date: _____ Year _____ Month _____ Day
Research Physician's Work Telephone: _____ Mobile Phone: _____