Official Title:

Robot-Assisted Arthroscopic Anterior Cruciate Ligament Reconstruction: A Prospective Randomized Controlled Trial

NCT Number:

[To be filled after registration]

Document Date:

March 25, 2025

You are invited to participate in this research study because you have been diagnosed with an anterior cruciate ligament (ACL) rupture and require surgical treatment. Your study doctor or research staff will explain the contents of this informed consent form in detail. Please read this document carefully before deciding whether to participate. If you are currently enrolled in another study, please inform your doctor.

Part I: Information for Participants

1. Project Introduction

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The title of this study is "Robot-Assisted Arthroscopic Anterior Cruciate Ligament Reconstruction," led by Dr. Hui Zhang and his team from the Department of Sports Injury at Beijing Jishuitan Hospital. The version of this informed consent form is JST IRB v1.3.

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This is an interventional clinical trial.

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Purpose of the Study:

The clinical efficacy of ACL reconstruction largely depends on the precision of femoral and tibial tunnel placement. Intraoperative fluoroscopy helps reduce tunnel placement deviation but relies heavily on the surgeon's experience. The limited imaging capacity of C-arms affects tunnel accuracy. Current orthopedic surgical robots also use fluoroscopy but suffer from poor image quality, and their design limits intraoperative movement, making arthroscopic procedures difficult. This study introduces a robotic system capable of integrating preoperative CT planning with real-time arthroscopic visualization. It aims to achieve accurate 3D navigation and tunnel placement, assist with tunnel drilling, and provide biomechanical tests like graft isometry and impingement prediction to enhance surgical outcomes and reduce postoperative graft failure rates.

2. Study Process

Participants will be randomly assigned to either the robot-assisted group or the conventional surgery group. Both groups will undergo arthroscopic ACL reconstruction. The robot-assisted group will use a robot system for tunnel planning and biomechanical testing. Both procedures are clinically feasible and safe. The robotic system will use CT and MRI data to plan tunnel positions, evaluate feasibility, predict graft isometry and impingement risk, assist in tunnel drilling, and perform axial shift measurement. Approximately 60 participants will be enrolled.

3. Study Duration

The study begins at hospitalization and continues for at least three days postoperatively. You may withdraw at any time without losing any entitled medical benefits. However, for your safety, we recommend discussing with your physician before withdrawal. If necessary, follow-up evaluations may still be conducted.

4. Inclusion and Exclusion Criteria

Inclusion: Adult patients with ACL rupture, age >16 years, closed epiphyses, informed consent provided, able to comply with clinical follow-up.
Exclusion: Combined ligament injuries, bilateral ACL rupture, poor soft tissue condition, uncontrolled infection, systemic diseases requiring urgent treatment.

5. Funding and Conflicts of Interest

The study is funded by the Capital Clinical Diagnosis and Treatment Technology Research and Transformation Project. There are no conflicts of interest.

Phone: 010-58516396

6. Research Institution and Investigator Information

The study is conducted at Beijing Jishuitan Hospital. The principal investigator is Dr. Hui Zhang, Chief Physician in the Department of Sports Injury. His team is among the earliest in China to perform arthroscopic ACL reconstructions, with over 20 years of experience and approximately 500 cases annually. They have contributed to national guidelines and clinical advancements in ACL treatment.

7. Potential Societal Benefits

The robotic system combines preoperative planning and surgeon-robot interaction to optimize femoral and tibial tunnel positioning, reduce graft impingement, and enable precise, stable reconstruction. It offers biomechanical assessments to

improve surgical quality and recovery, ultimately enhancing quality of life and enabling wider adoption of advanced techniques with socioeconomic value.

8. Potential Benefits to Participants

Participants may receive advanced surgical treatment and standardized postoperative care by experienced surgeons. Regardless of group assignment, patients benefit from expert management. Study-related procedures incur no additional cost, and no financial compensation is provided. Treatment costs match standard care.

9. Risks and Discomfort

ACL reconstruction is complex, involving autograft harvesting, bone tunnel creation, and possibly meniscal repair. Postoperative effects may include pain, stiffness, or muscle weakness, which typically improve with rehabilitation. All procedures follow standard protocols and are conducted by experienced surgeons. The robotic system introduces minimal risk, with validated safety measures. In case of study-related injury, timely treatment will be provided and compensation arranged per national laws. Insurance is recommended.

10. Emergency Measures

In emergencies, contact Dr. Hui Zhang at 010-58516396. Treatment plans may be adjusted accordingly.

11. Alternative Treatments

If you opt out of the study, you may undergo conventional arthroscopic ACL reconstruction.

12. Confidentiality

Your records will be kept confidential as required by law. Identifiable information such as your name or ID number will not be disclosed outside Beijing Jishuitan Hospital unless required by law. De-identified data will be used for analysis and publication. Regulatory agencies and the ethics committee may audit the records.

13. Investigator Contact

If you have questions, please contact Dr. Hui Zhang at 010-58516396.

14. Participant Rights

Participation is voluntary. You may decline or withdraw at any time without penalty or loss of medical rights. If adverse events occur or your doctor deems withdrawal necessary, you will be informed and guided through alternatives. If needed, you may undergo final evaluations before discontinuation.