

Combined surgical approach: simultaneous reconstruction of anterior cruciate ligament and anterolateral structures through a modified single femoral tunnel technique

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| Submission date 27/02/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/05/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/08/2025 | Condition category Surgery | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Anterior cruciate ligament (ACL) injury is a very common sports injury. It is reported that there are about 2 million cases of ACL injuries worldwide each year. ACL reconstruction (ACLR) is the main and standard surgery for ACL injury. Despite the development of techniques, grafts, and rehabilitation, 10-30% of patients still have rotational instability after isolated ACLR, increasing the risk of graft rupture, affecting patient movement and delaying patient recovery. The aim of this study is to explore the clinical outcomes of combining ACL reconstruction and anterolateral structure (ALS) reconstruction through a modified single femoral tunnel in patients with a high risk of clinical failure.

Who can participate?

Patients aged under 50 years undergoing ACLR combined with ALS reconstruction from December 2018 to August 2022

What does the study involve?

All procedures were performed by the same experienced surgeon. All patients received similar perioperative management programs. Measurements included function, stability and safety evaluations at different time points (preoperative, postoperative, 3 months, 6 months, 1 year, 2 years, 3 years and more).

What are the possible benefits and risks of participating?

Possible risks of the surgery include deep venous thrombosis, knee joint stiffness, and acute knee infection.

Where is the study run from?

Luoyang Orthopedic Hospital of Henan Province, Orthopedic Hospital of Henan Province (China)

When is the study starting and how long is it expected to run for?
June 2017 to December 2022

Who is funding the study?

1. National Natural Science Foundation of China
2. Project of Science and Technology of Henan Province (China)

Who is the main contact?

Guorui Cao, 13688172272@163.com

Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Meniscus surgical treatment demonstrated inferior clinical outcomes as no meniscus injury with simultaneous combined anterior cruciate ligament and anterolateral structure reconstruction: a case-controlled study

Study objectives

Patients without meniscus injury have superior clinical outcomes. Meniscus repair and partial meniscectomy with simultaneous anterior cruciate ligament (ACL) and anterolateral structure (ALS) reconstruction could result in equivalent clinical outcomes.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/10/2023, Luoyang Orthopedic Hospital of Henan Province (82 Qiming South Road, Luoyang, 621000, China; +86 (0)37963536160; smxwx@163.com), ref: 2023ZXKT005-01

Study design

Retrospective case controlled study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Training facility/simulation

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Combined anterior cruciate ligament and anterolateral structure reconstruction

Interventions

From December 2018 to August 2022, a total of 62 patients with ACL injury were enrolled in this study. All patients were associated with a high risk of clinical failure, meeting the indications of ALS augmentation, including 47 males and 15 females, aged 16-52 years with an average age of 29.3 ± 9.2 years. All patients accepted arthroscopic single-bundle ACL reconstruction and ALS reconstruction using hamstring autograft through a modified single femoral tunnel. Perioperative clinical outcome measurements comprised function, stability and safety evaluations at different time points (preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more). The functional evaluation included the Lysholm score, Tegner activity scale, and subjective and objective International Knee Documentation Committee (IKDC) score.

Intervention Type

Procedure/Surgery

Primary outcome measure

Knee-specific symptoms measured using the Lysholm score at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more

Secondary outcome measures

1. Sports activity measured using the Tegner activity scale at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more

2. Knee function measured using the subjective and objective International Knee Documentation Committee (IKDC) score at preoperative, postoperative 3 months, 6 months, 1 year, 2 years, 3 years and more

Overall study start date

27/06/2017

Completion date

30/12/2022

Eligibility

Key inclusion criteria

1. Patients with ACL and ALS reconstruction through single femoral tunnel
2. Aged 16-52 years
3. No history of previous ipsilateral knee injury and surgery

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Upper age limit

52 Years

Sex

Both

Target number of participants

103

Total final enrolment

62

Key exclusion criteria

1. Multiple ligament injuries
2. ACL rupture associated with fracture
3. ACL revision
4. Significant degree of osteoarthritis (OA) or cartilage damage
5. Skeletally immature or incomplete medical records

Date of first enrolment

01/12/2018

Date of final enrolment

30/08/2022

Locations

Countries of recruitment

China

Study participating centre

Luoyang Orthopedic Hospital of Henan Province

82 Qiming South Road

Luoyang

China

471000

Sponsor information

Organisation

Luoyang Orthopedic-Traumatological Hospital of Henan Province

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China (82104896)

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

Project of Science and Technology of Henan Province

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

15/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Guorui Cao (13688172272@163.com)

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 13/08/2025 | 14/08/2025 | Yes | No |