

Surgical versus non-surgical treatment of anterior cruciate ligament (ACL) injuries: a randomised prospective clinical trial

Submission date 21/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/05/2025	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Surgical versus non-surgical treatment of anterior cruciate ligament (ACL) injuries: a randomised prospective clinical trial

Acronym

KANON

Study objectives

To compare the short-term (2 years) and long-term (5 years) outcome of surgical and non-surgical treatment of acute ACL disruptions in a physically active population. The primary effective hypothesis will be evaluated with a disease-specific patient-relevant questionnaire (Knee injury and Osteoarthritis Outcome Score [KOOS]), the number of treatment failures and the return to pre-injury activity level.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Anterior cruciate ligament rupture of the knee

Interventions

Surgery and structured rehabilitation compared with structured rehabilitation only.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. KOOS and SF-36 patient-administered questionnaire scores, and number of treatment failures at 2 and 5 years
2. Number and grade of joint changes, including bone marrow and meniscus lesions, assessed by radiographs and MRI at 5 years

Secondary outcome measures

Knee joint laxity, physical activity level, and molecular markers of joint tissue turnover

Overall study start date

15/01/2002

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Age 18-35 at entry
2. A history of a knee sprain not more than 4 weeks before inclusion
3. An ACL insufficiency as determined by clinical examination (positive Lachman test and positive pivot shift) and a complete ACL tear as visualized on Magnetic Resonance Imaging (MRI)
4. Activity level 5-9 by Tegner classification
5. A plain radiographic examination with normal joint status or with a small avulsed lateral fragment or grade 1 osteophyte or grade 1 joint space narrowing as determined by the Osteoarthritis Research Society International (OARSI) atlas

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

35 Years

Sex

Both

Target number of participants

120

Total final enrolment

121

Key exclusion criteria

1. Pregnancy
2. Earlier major knee injury or knee surgery other than diagnostic arthroscopy on either knee
3. One of the following associated injuries on either knee:
 - 3.1. Grade III medial collateral ligament injury
 - 3.2. An injury to the lateral/posterolateral ligament complex with significantly increased laxity
 - 3.3. Posterior Cruciate Ligament (PCL) injury
 - 3.4. An unstable meniscus tear that requires repair and post-operative treatment interfering with the rehabilitation protocol
 - 3.5. Bi-compartmental extensive meniscus resections
4. A cartilage injury representing a full thickness loss down to bone visualized on MRI
5. Joint space narrowing (JSN) grade 1 combined with osteophytes or JSN grade 2 or greater in the index or contralateral knee as classified by the OARSI atlas
6. A history of deep vein thrombosis (DVT) or a disorder of the coagulative system
7. Refusing to undergo radiological or surgical interventions due to claustrophobia, etc.
8. General disease that affects physical function or systemic medication/abuse of steroids
9. Any other condition or treatment interfering with the completion of the trial, including patients with metal devices or motion disorders etc. that will be unable to complete MRI examination

Date of first enrolment

15/01/2002

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

Sweden

Study participating centre

Lund University Hospital

Lund

Sweden

SE-22185

Sponsor information**Organisation**

Lund University Medical Faculty (Sweden)

Sponsor details

PO Box 117

Lund

Sweden

SE-22100

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Sponsor type

Industry

Website

<http://www.med.lu.se>

ROR

<https://ror.org/012a77v79>

Funder(s)**Funder type**

Industry

Funder Name

Medicinska Fakulteten, Lunds Universitet

Alternative Name(s)

Faculty of Medicine, Lund University

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Region Skåne (Sweden)

Funder Name

Pfizer

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Swedish Research Council (Sweden)

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Swedish Research Council for Sports Medicine (Sweden)

Funder Name

Swedish Rheumatism Association (Sweden)

Funder Name

Zoega and Gorthon Foundations (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative study results	10/08/2009		Yes	No
Results article	results	22/07/2010		Yes	No
Results article	results	24/01/2013		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	01/05/2016		Yes	No
Other publications	exploratory analysis	01/09/2017		Yes	No
Other publications	exploratory analysis	01/11/2017		Yes	No
Results article	secondary analysis results	01/05/2020	29/10/2019	Yes	No
Results article	results	04/02/2021	09/02/2021	Yes	No
Results article	results on association between meniscal integrity and early bone surface area changes	03/03/2021	08/03/2021	Yes	No
Results article	5-year follow up results	09/03/2021	10/03/2021	Yes	No
Results article	Secondary analysis of participants randomised to rehabilitation and optional delayed ACL reconstruction (ACLR) or early ACLR and rehabilitation	03/11/2022	04/11/2022	Yes	No
Results article	Exploratory analysis	03/01/2025	07/01/2025	Yes	No
Results article	Association Between ACL Continuity on Magnetic Resonance Imaging at 5 Years After an Acute ACL Rupture and 11-Year Outcomes: A Secondary Analysis From the KANON Trial	19/05/2025	20/05/2025	Yes	No