ISRCTN84752559 https://doi.org/10.1186/ISRCTN84752559

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

Submission date	Recruitment status	[_] Prospectively registered
21/10/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2025	Skin and Connective Tissue Diseases	

Plain English Summary
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 hypothesis
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 primarily 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

Condition
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

Overall study end date
31/12/2005

Eligibility

Participant 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

Participant 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

Recruitment start date
15/01/2002

Recruitment end date
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
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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