

Computer assisted surgery versus conventional arthroscopic anterior cruciate ligament reconstruction: a prospective randomised clinical trial

Submission date 08/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/03/2021	Condition category Musculoskeletal 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

Study information

Scientific Title

Computer assisted surgery versus conventional arthroscopic anterior cruciate ligament reconstruction: a prospective randomised clinical trial

Study objectives

An Anterior Cruciate Ligament (ACL) reconstruction can take place more accurately with Computer Assisted Surgery (CAS) than a conventional arthroscopic reconstruction with regard to tunnel position.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local medical ethics committee on the 12th September 2006 (ref: MEC-2006-223).

Study design

Randomised, active-controlled, parallel group, single blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Rupture, anterior cruciate ligament

Interventions

Arthroscopic ACL reconstruction, randomised in 45 conventional (usual care), and 45 CAS patients.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Planned tunnel position versus actual achieved tunnel position of the ACL transplant (by Computed Tomography [CT]).

Secondary outcome measures

1. Difference in change in International Knee Documentation Committee (IKDC) subjective knee score
2. Difference in change in Knee injury and Osteoarthritis Outcome Score (KOOS)
3. Difference in change in knee pain (Visual Analogue Scale [VAS] for pain)
4. Difference in change in knee complaints (Lysholm score)
5. Difference in change in sport activity (Tegner score)
6. Difference in change in objective instability of the knee (KT1000 arthrometer)
7. Difference in change in objective muscle strength (Biodex)
8. Difference in satisfaction of the treatment

Overall study start date

01/12/2006

Completion date

01/12/2010

Eligibility**Key inclusion criteria**

1. All patients with an ACL rupture who are indicated for a reconstruction
2. Aged more than 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

90

Total final enrolment

100

Key exclusion criteria

1. Patients who are unable to understand Dutch written language
2. Patients who are unable to follow the regular postoperative controls

Date of first enrolment

01/12/2006

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

P.O. Box 2040

Rotterdam

Netherlands

3000 CA

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details

Department of Orthopaedics

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Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****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		05/09/2012	26/03/2021	Yes	No