ISRCTN40231111 https://doi.org/10.1186/ISRCTN40231111

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

Registration date
08/02/2007

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

NL856 (NTR870)

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