

Specific Orientation in ACL Reconstruction, a Clinical Pilot Study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24570

Source

Nationaal Trial Register

Brief title

SONAR - Clinical Pilot Study

Health condition

ACL injury

Sponsors and support

Primary sponsor: Univeristy Medical Center Groningen

Source(s) of monetary or material Support: Samenwerkingsverband Noord Nederland

Intervention

Outcome measures

Primary outcome

Difference between planned and achieved femoral tunnel position

Secondary outcome

none

Study description

Background summary

Accurate Femoral tunnel positioning remains challenging in ACL reconstruction. 80% of technical failures leading to graft failure compromises femoral tunnel misplacement. A patient specific, 3D printed guide for use during ACL reconstruction has been developed. The feasibility and accuracy of the device has been proven in a cadaver study. This study aims to determine the in vivo accuracy of the patient specific 3D printed guide for femoral tunnel positioning during ACL reconstruction.

Study objective

The patient specific 3D printed femoral guide is accurate

Study design

1. Enrollment. The routinely performed MRI scan of the knee will be used to create a 3D printed patient specific guide for femoral tunnel placement during ACL reconstruction.
2: Day of Surgery: a MRI scan will be performed postoperatively to determine the achieved femoral tunnel position.
The MRI scan and femoral tunnel will be segmented using Mimics Software.
The achieved femoral tunnel position will be compared to the planned femoral tunnel position using Polygon software.

Intervention

ACL reconstruction using the patient specific 3D printed femoral guide

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Age > 16 years
Primary ACL injury requiring ACL reconstruction

Exclusion criteria

No pre-operative MRI available

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2020
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 26-08-2020

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8942
Other	METC UMCG : METC2015/057

Study results