4D Dynamic CT scan for the evaluation of Patellofemoral Instability
Optimize to lower the radiation dose

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To perform a pilot study to optimise reproducible dynamic 4D CT scanning of the knee in evaluating patellar tracking and to reduce the radiation dose needed. The outcome of this pilot study will be used to perform a study on healthy subjects to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON45682

Source
ToetsingOnline

Brief title
4D CT Knee pilot

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
displacement of the kneecap, Patellofemoral instability

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 4D Dynamic, Computed Tomography, Dose reduction, Patellofemoral instability

Outcome measures

Primary outcome

The main study parameter is the lowest possible dose to have an accurate measurement of knee movement in a dynamic CT scan, to be able to perform studies on healthy subjects.

Secondary outcome

The secondary endpoints are the knee movements as mentioned in the main study parameter; relation between the flexion angle of the knee, the TTTG distance, tibial rotation, patellar tilt and mediolateral displacement of the patella.

Study description

Background summary

A patellar dislocation is one of the most common acute knee disorders in children and adolescents. One of the main reasons for the instability is an excessive tibial tubercle-trochlear groove (TTTG) distance. In order to solve this problem, a tibial tubercle transposition can be performed. However, the normal values for TTTG and the amount of correction that should be performed remain uncertain. The reported normal values in asymptomatic individuals vary substantially and are measured in complete extension of the knee. However, the TTTG is depending on the flexion angle of the knee. This is probably due to a relation between the TTTG and tibial rotation. To investigate this, we want to make the new technique of dynamic 4D CT scanning of the knee applicable with the lowest dose possible. This will provide a way to better understanding of patellofemoral tracking and improve the surgical planning.

Study objective

To perform a pilot study to optimise reproducible dynamic 4D CT scanning of the knee in evaluating patellar tracking and to reduce the radiation dose needed. The outcome of this pilot study will be used to perform a study on healthy

subjects to determine normal values of dynamic patellar tracking.

Study design

Prospective single centre observational study

Study burden and risks

All patients will have one 4D dynamic CT scan of both knees. This CT is associated with an ionising radiation dose of 0.3 millisievert (mSv), compared to normal preoperative CT scan of the knee of 0.02 mSv. This will burden a trivial risk compared to the natural background radiation in the Netherlands (2mSv).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 18 years and older.
* Recurrent patellofemoral instability, in which the conservative management has failed.
* A preoperative CT scan is required.

Exclusion criteria

* Patients below age of 18 years.
* Patients with prior surgery of the knee.
* Subjects not able to active flex and extend the knee.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	05-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL60392.091.17