4D dynamic CT of the knee, kinematics of the normal, healthy knee.

Published: 20-07-2020
Last updated: 08-04-2024

The objective of this study is to accurately determine the kinematics of healthy subjects to be able to compare them with patients suffering from patellofemoral instability, by scanning volunteers without knee complaints using 4D dynamic CT imaging...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49438

Source
ToetsingOnline

Brief title
4DCTHK

Condition

- Joint disorders

Synonym
Patella luxation, 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: 4DCT, dynamic, healthy, volunteers

Outcome measures

Primary outcome

The primary outcome measure is the determination of the healthy, normal patellofemoral and tibiofemoral kinematics based on dynamic CT. For this purpose the patella center - trochlear groove distance is examined.

Secondary outcome

The second outcome measure in this study is the Kujale Knee Score (KKS), a patient reported assessment of patellofemoral disorders that evaluates subjective symptoms and functional limitations.

Study description

Background summary

This study complements an earlier approved study (NL60392.091.17 / CMO 2017-3200). Patellofemoral instability is a common knee disorder in children and young adults. In patients with patellofemoral instability the patella (=kneecap) can luxate from the femoral trochlea (=groove). The disorder is associated with pain, inability to ambulate, gait alteration and is linked to early onset osteoarthritis in the patellofemoral joint. Primary treatment is primarily conservative. However, if dislocations are recurrent, orthopaedic surgery is considered to stabilize the joint. Although the surgical outcome is generally good, a significant part of patients keeps having patellar dislocations as well as an unstable feeling.
As part of the work-up for surgery currently a conventional CT study scan is performed. As the underlying clinical problem of patellofemoral instability is dynamic in nature, the conventional CT lacks important information on the dynamic behaviour of the femur, patella and tibia. In the beforementioned study we investigated the use of 4D dynamic CT imaging to automatically determine knee kinematics while simultaneously establishing the optimal dose for this purpose. With this newly established lower dose and optimized protocol, we want to determine the baseline kinematics of normal, healthy

knees. This allows us to compare the kinematics of patients with the healthy baseline, enabling us to improve surgical planning for patients with patellofemoral instability and in the end, improve the clinical outcome.

Study objective

The objective of this study is to accurately determine the kinematics of healthy subjects to be able to compare them with patients suffering from patellofemoral instability, by scanning volunteers without knee complaints using 4D dynamic CT imaging. .

Study design

Prospective single centre observational study

Study burden and risks

The risk of participating in this research is low.

During the research the participant will be exposed to a (very) small amount of ionising radiation (X-rays). The total radiation dose to which the participant will be exposed during this research is 0.08 mSv. By way of comparison, the background radiation in the Netherlands due to natural radiation sources is 2mSv per inhabitant per year. A transatlantic flight involves a dose of 0.1 mSv.

The risk of this additional radiation load is therefore low.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Subject is between 18 and 35 years of age. Subject must not have prior injuries, surgery to the knee, or any knee complaints. Subject hast signed informed consent and has no more questions about the protocol.

Exclusion criteria

Subject is younger than 18 years. Subject has prior injuries to the knee or a congenital disorder. Subject is unable to do a full extension /flexion movement. Subject is pregnant. Subject has severe valgus coronal alignment of the leg.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-11-2020
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2020
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	NL72784.091.20

Study results

Date completed:	22-06-2021
Actual enrolment:	100

Summary results
Trial is onging in other countries