Knee laxity at 0 * , 30 * and 90 * of flexion measured in the normal older healthy knee

Published: 16-12-2015
Last updated: 19-04-2024

Primary Objective: To determine the varus and valgus laxity in extension (0 *), mid-flexion (30 *) and flexion (90 *) in the normal older healthy knee from subject equal aged to the population of patients who received a total knee prosthesis in the...

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

Summary

ID

NL-OMON42759

Source
ToetsingOnline

Brief title
Knee laxity in mid-flexion

Condition

- Joint disorders

Synonym
Mid-flexion knee laxity; reference values

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: eigen middelen Sint Maartenskliniek.

Intervention

Keyword: Knee laxity, Mid-flexion, Varus-valgus laxity

Outcome measures

Primary outcome

The main outcome parameter is varus and valgus laxity of the knee at 0 *, 30 * and 90 * flexion. For varus and valgus flexion a custom made stress device will be used to stress the knee. With this device the subject lay supine with his/her lower leg on a plateau with the knee flexed in 0 *, 30 * and 90 *. With the use of a 5 kilogram weight at 30 cm from the joint line and a pulley a moment of 15 Nm will be applied at the knee joint. The knee will stressed medially and laterally. For each subject, nine roentgenograms (three in 0 *, three in 30 * and three in 90 *) will be taken with medial, lateral and no stress applied, under fluoroscopic guidance with the roentgen ray direction parallel to the tibia joint surface.

Secondary outcome

* Demographic data

* Patient reported outcome score: Tegner activity score

* Clinician reported outcome score:

* - Knee Society Score assessed as defined by

Insall

* - Anterior and posterior translation of the tibia was

measured in 20 *, 30 * and 90 * flexion using the Rolimeter.

* Functional outcome:

* Knee power output measured with the Leg Extensor Power Rig

Study description

Background summary

The aim of TKA using a ligament-guided implantation technique is to restore knee function and kinematics of the arthritic knee to a normal, healthy level, on guidance of the intact knee ligaments. Therefore reference values of an equal aged healthy (non-arthritic) control group were needed to compare these values with the TKA population. Heesterbeek et al. (2006) performed a study to quantify the amount of varus and valgus laxity in extension and flexion (70 *) in the healthy older knee.

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Study objective

Primary Objective:

To determine the varus and valgus laxity in extension (0 *), mid-flexion (30 *) and flexion
(90 *) in the normal older healthy knee from subject equal aged to the population of patients who received a total knee prosthesis in the Sint Maartenskliniek.

Secondary Objective(s):

The secondary objective of this study is to assess AP-laxitiy, the Knee Society Clinical and Functional Rating System and Knee function measured with the Leg Extensor Power Rig of the normal older, non-arthritic knee.

Study design

The present study is a cross sectional study to determine reference values of knee laxity measured at 0 *, 30 * and 90 * flexion in the normal older healthy knee from subjects equal aged to the population of patients who received a TKA. Participants will be assessed at one occasion.

Study burden and risks

Healthy subjects are asked to visit our clinic once. The extra amount of time that a subject invests in the study is about 1 hour. Prior to the visit the subjects are asked to fill in the questionnaire, during the visit X-rays will

be taken. Questionnaires do not bring any extra burden. The radiation of nine radiographs will be set to a minimum and therefore the total amount of radiation falls within the limits of the IRP (International Commission of Radiological Protection.) The Leg extensor power rig is a standardized and save device used for measuring knee function power output.

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

* Subject is between 50 and 75 years old
* Subject has nog osteoarthritis or rheumatoid arthritis in one or both knees
* Subject has no history of knee injury, especially knee ligament injury
* Subject is living independently (e.g. not in a nursing home)
* Subject is able to walk for at least 1 hour without support (indicating good knee function)

Exclusion criteria

* Subject has a hip arthrodesis
* Subject has a hip prosthesis
* Subject has a BMI >35
* Subject has knee flexion <90 *
* Subject has ligament problems or varus or valgus leg
* Subject has low bone density
* Subject lives further than 50 km from the Sint Maartenskliniek

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	16-12-2015
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	07-04-2016
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL55385.048.15

Study results

Date completed:	02-08-2016
Actual enrolment:	40