Scorpio PS vs Scorpio NRG PS total knee arthroplasty. Comparative investigation of function.

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

Summary

ID

NL-OMON34832

Source
ToetsingOnline

Brief title
Scorpio PS vs Scorpio NRG PS

Condition

- Joint disorders

Synonym
knee arthrosis knee arthoplasty

Research involving
Human

Sponsors and support

Primary sponsor: Stryker SA
Source(s) of monetary or material Support: Stryker

Intervention

Keyword: function, kneeprostheses, painreduction

Outcome measures

Primary outcome

As primary study parameter the maximal flexion will be compared between the two

prostheses.

Secondary outcome

As secondary study parameters the complications will be registered and a

comparison will be done of the chair raise and stair climb test

with the corresponding pain score, and the operation time

Study description

Background summary

Knee prostheses consist of several different kinds of design developed to optimize a certain part of the function of the knee. standard knee prosthesis consists of a femoral component a tibial component and an insert in between these two to make movement as smooth as possible.
Dependent on the design of the several parts of a prosthesis the main aim can be optimising total flexion, better possibility to kneel, or numerous other specific functions.
The NRG knee prosthesis as a specific design developed to optimize maximum flexion en decrease post-operative anterior knee pain

Study objective

This new developed knee prosthesis will be compared to the standard scorpio PS knee prosthesis. In this comparison it will be examined if the changes in design really do improve function and deminish pain. Allso patella tracking and patella tilting will be copared.

Study design

It is a prospective single center single blind randomized clinical trial. After pre-operative screening and X-rays 88 patients of the AZM will have a normal total knee replacement operation. 44 patients will get the scorpio NRG knee prosthesis and 44 patients will get the Scorpio PS knee prosthesis. Post-operatively the patients will have a check up at 6 wkeeks 3 months 6 months 1 year 2 years and 5 years. At these check ups a knee society score, a chair raise and stair climb test will be done, complications will be registered, a womac patient self evaluation will be done and X-rays will be taken.

Intervention

All patients will have a total knee replacement operation during which the study knee or the control knee prosthesis will be implanted

Study burden and risks

The risks for the patients are the standard risks of a total knee replacement surgery. A surgery which the patient also will have if he/she does not participate in the study.
At each visit two extra X-rays will be taken of which the radiation exposure will be largely beneath the allowed exposure.

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 between 18 and 80 years
male and non-pregnant female
patients requiring a primary TKA

Exclusion criteria

patients with BMI higher than 35
patients with active infection
patients with malignancy
patients requiring revision surgery of a previous implanted total knee system

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2010
Enrollment:	88
Type:	Actual

Medical products/devices used

Generic name:	The Scorpio PS knee prosthesis and the Scorpio NRG PS knee prosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31488.068.10

Study results

Date completed:	15-11-2018
Results posted:	21-04-2020
Actual enrolment:	88

First publication
14-10-2019