Scorpio NRG® prospective, open-label, post-market international multicentre outcome Study

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

Summary

ID

NL-OMON47763

Source
ToetsingOnline

Brief title
Scorpio NRG® study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
total knee replacement

Research involving
Human

Sponsors and support

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

Intervention

Keyword: effect of component design, long time evaluation, patient satisfaction, total knee replacement

Outcome measures

Primary outcome

1. clinical evaluation: preoperative, peri-oprative, potopreative prior to

discharge and follow-up

2. patient scores:

KOOS (Knee injury and osteoarthritis outcome score) and SF-36 for patient

satisfaction

LEAS (Lower Extemety Activity Scale) for patient activity

EQ5D (Quality of Life)

Secondary outcome

see primary parameters

Study description

Background summary

This document is a protocol for a clinical outcome study. This study will be conducted in
compliance with the protocol, Good Clinical Practice Guidelines, associated regulations and all
applicable research requirements.

Today total knee joint replacements are routinely implanted with total knee arthroplasty being
one of the most successful joint reconstructions. The number of total knee replacements is
rising worldwide and patients are increasingly younger at the time of implantation. The
developments of the implant design, as well as the improvement of instruments, over the last
decades enable sound and reliable results. With increasing success of joint replacement and
decreasing age of patients, the expectations of total knee arthroplasty are constantly on the rise.
Patients anticipate reduced painkiller, long lifetime of the implant with high functionality and a
great range of motion to carry out daily activities and sports. Apart from regaining a lifestyle
without major knee pain, some cultural and religious aspects (e.g. kneeing while praying) where
deep flexion is required, are a challenge for modern knee-systems.
The Scorpio NRG® Knee System has been designed with these activities in mind. Scorpio
NRG® has a greater internal and external rotational freedom throughout the full range of motion
when compared to other modern knee replacement designs. Traditional insert designs utilize a
less functional partial rotary arc, thus limiting the overall kinematic function of the knee. The
Scorpio NRG® tibial insert*s articulating surface uses a Spherical Arc motion in order to realize
greater freedom. By combining a single M/L radius and a Spherical Arc, Scorpio NRG® allows
for greater rotational freedom without restricting the tibio-femoral contact area. Freedom of
rotation is one of the most essential factors in the design of a successful total knee replacement,
thus allowing the patient*s ligaments to govern motion of the knee.
Furthermore the component design can contribute to patient*s activity level by providing joint
stability and improved function. While traditional knee implants are designed with several axes
of rotation that may create mid-flexion instability during the transition between radii, a single axis
and single radius design can provide consistent collateral ligament isometry and stability
throughout the range of motion.
In this outcome study of the Scorpio NRG® knee system we except improvement of a patients

lifestyle and activities. This study evaluates patients for 5 optional 7 years post surgery. The
focus of this study is to evaluate the effect of component design on functional performance and
the patient*s satisfaction. Thus the knee society score and the SF-36 is used. Further measure
being used includes the comparative postoperative with preoperative Lower Extremity Activity
Scale (LEAS) and in addition the Knee Injury and Osteoathritis Outcome Score (KOOS) and EQ5D to
evaluate the quality of life.

Study objective

The objective of this study is to collect basic function and patient satisfaction data
for observation and analysis.
Specific objectives include the following:
Evaluate the effect of component design on functional performance by comparing postoperative
Knee Society Scores with preoperative.
Evaluate the effect of component design on patient activity by comparing postoperative Lower
Extremity Activity Scale (LEAS) with preoperative.
Evaluate patient satisfaction using SF-36® Health Survey.
Evaluate quality of life using Knee Injury and Osteoathritis Outcome Score (KOOS) and EQ5D.

Study design

A prospective, open-label design will be employed. The study is international and multicentre.

Study burden and risks

As in any surgical procedure, certain risks are associated with total joint arthroplasty. These risks include but are not limited to: anaesthetic ans post anaestehtic reactions (such as hyperaemiea), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves, trochanteric or femoral fractures during implantation,perforation of the cortical wall, or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, disklocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication.
Pre-clinical, clinical and mechanical testing of the used implants indicate that the above mentioned risks should not occur at a rate greater than that for

any other type of total knee arthroplasty reported in the literature.

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

1) Patient is able to understand the meaning of the study and is willing to sign the EC approved, study specific Informed Patient Consent Form.;2) The subject is a male or non-pregnant female between 40 and 75 years of age.;3) The subject requires a primary total knee replacement.;4) Patients with osteoarthritis or posttraumatic arthritis (no rheumatoid arthritis);5) The subject has intact collateral ligaments.;6) The subject is willing and able to comply with postoperative scheduled clinical and radiographic evaluations and rehabilitation.;7) The subject is capable of understanding the patient scores in the national language.

Exclusion criteria

1) The subject is morbidly obese, defined as Body Mass Index (BMI) of > 40.;2) The subject has a history of total or unicompartmental reconstruction of the affected joint.;3) The subject will be operated bilaterally.;4) Patients who had a Total Hip Arthroplasty (THA) on contralateral and/or ipsilateral side within the last year that is considered to have an unsatisfactory outcome (Patients with contralateral and/or ipsilateral THA > 1 year ago with good outcome can be included in the study).;5) Patients who had a Total Knee Arthroplasty (TKA) on contralateral
side within the last 6 months that is considered to have an unsatisfactory outcome. (Patients with contralateral TKA > 6 months ago with good outcome can be included in the study).;6) Patients who will need lower limb joint replacement for another joint within one year.
7) The subject has had a high tibial osteotomy or femoral osteotomy.;8) The subject has a neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device.;9) The subject has a systemic or metabolic disorder leading to progressive bone deterioration.;10) The subject is immunologically suppressed or receiving steroids in excess of normal physiological requirements.;11) The subject*s bone stock in compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis.;12) The subject has had a knee fusion to the affected joint.;13) The subject has an active or suspected latent infection in or about the knee joint.;14) Proven or suspected hypersensitivity to one or more than one of the device materials (see Appendix 10 table of chemical composition).;15) Female patients planning a pregnancy during the course of the study.;16) The subject is a prisoner.;17) severe deformities: varus/valgus deformity >10° (mech. axis), bowed femur
> 20 degree, as well as 10 degrees flexion contracture

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-01-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	total knee replacement
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-08-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-03-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	21-10-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-12-2014

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL25443.100.08

Study results

Date completed:	11-12-2019
Actual enrolment:	143