

Stryker NTX registry

Submission date 21/01/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/03/2021	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The aim of the study is to provide information on safety and efficacy of three types of knee prostheses, manufactured by Stryker.

Who can participate?

Up to 16 hospitals/clinics will participate in the study.

Up to 1600 patients will be included in the study (20-100 per centre).

All patients of one of these centre who are eligible for a total knee arthroplasty replacement surgery with one of the three Stryker knee prostheses (Scorpio NRG/X3, Triathlon/X3, Triathlon PKR/X3) and who have consented to participate can be enrolled in the study.

What does the study involve?

This is an observational study. That means that all the patients participating in the study will be followed according to the current practice of their surgeons. The study will just collect the data (that will be anonymized) to be able to perform statistical analysis and assess the safety and efficacy of the knee prostheses.

What are the possible benefits and risks of participating?

This study does not provide additional risk for the patients, as all the patients are followed according to the common practice of their surgeons. No payment will be done to the patient. The patients will be followed according to the common practice of all the investigators.

Where is the study run from?

This study takes place in Germany, Luxembourg, and the UK

When does the study take place?

June 2012 to December 2024

Who is funding the study?

Stryker European Operations BV (Netherlands)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02525562

Protocol serial number

K-S-044

Study information

Scientific Title

Scorpio NRG, Triathlon Total Knee, Triathlon PKR with X3 Insert International Multicentre Outcomes Register

Acronym

NTX

Study objectives

There is no specific study hypothesis as this is an observational study.

The objective is to provide outcomes information with regard to surgical and implant performance and patient clinical outcomes of the patients who are eligible for a either a Total Knee Arthroplasty (TKA) replacement surgery involving either:

1. Scorpio NRG Total Knee System with X3 insert
2. Triathlon Total Knee System with X3 insert

or

1. Partial Knee Resurfacing (unicompartmental knee arthroplasty, UKA) involving:
2. Triathlon PKR (Partial Knee Resurfacing) System with X3 insert

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. CH Luxembourg, Clinique d'Eich, Luxembourg: CNER (Comité National d'Ethique de Recherche), 14/09/2011, ref: #201109/01
2. Maria Middelaes, Belgium: AZ Maria Middelaes Ethic Committee, 07/12/2011, ref: #PB/nm/2011.77
3. Erler Klinik, Nurnberg, Germany: Ethik-Kommission der Bayerischen Landesärztekammer, 02/11/2011, ref: #11112
4. Media Park Klinik, Köln, Germany: Ärztekammer Nordrhein Ethikkommission, 04/06/2012, ref: #2012132

All other centres will seek ethics approval before recruiting participants

Study design

European multicentre prospective follow-up of a consecutive series of patients

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis, rheumatoid arthritis, avascular necrosis, traumatic arthritis or other diseases requiring total knee arthroplasty or partial knee resurfacing.

Interventions

It is anticipated that the patients shall be recruited within a 12 month period at each participating centre. The length of surveillance and patient visit schedule is based on the routine procedures of the institution. The surveillance system is set-up to record data at pre-operative, intra-operative and 1 year, 3 years, 5 years, 7 years and 10 years follow-up.

Safety during follow-up and Survivorship as described by Kaplan-Meier survival curves

Standard clinical parameters and KSS (Knee Society Score) as well as patient questionnaires [EQ5D (EuroQol Group) and KOOS (Knee Injury and Osteoarthritis Outcome Score)] pre-operatively and each follow-up visit.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

1. Scorpio NRG Total Knee System with X3 insert
2. Triathlon Total Knee System with X3 insert
3. Triathlon Partial Knee Resurfacing with X3 insert

Primary outcome(s)

Survivorship of the implant; pre-operative, intra-operative and 1 year, 3 years, 5 years, 7 years and 10 years follow-up

Key secondary outcome(s)

1. Any adverse event
2. Knee Society Score (KSS)
3. Knee Injury and Osteoarthritis Outcome Score (KOOS)
4. EuroQol Group Score (EQ5D)

Pre-operative, intra-operative and 1 year, 3 years, 5 years, 7 years and 10 years follow-up

Completion date

25/03/2021

Eligibility

Key inclusion criteria

1. Patients requiring primary Total Knee Arthroplasty (TKA), suitable for the use of the Scorpio NRG with X3 insert or Triathlon Total Knee System with X3 insert, or, patients requiring partial knee resurfacing (unicompartmental knee) suitable for the use of the Triathlon PKR (Partial Knee Resurfacing) System with X3 insert
2. Patients who understand the conditions of the outcomes registry and are willing and able to comply with the standard post-operative evaluations and the prescribed rehabilitation
3. Patients who signed the Informed Consent Form (approved by Ethics Committee if required) prior to surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/06/2012

Date of final enrolment

11/03/2014

Locations

Countries of recruitment

United Kingdom

England

Germany

Luxembourg

Study participating centre

CH Luxembourg

Luxembourg

L-1210

Study participating centre

Erler Klinik

Nürnberg

Germany

90429

Study participating centre

Alexandra Hospital

Redditch

United Kingdom

B98 7UB

Sponsor information

Organisation

Stryker European Operations BV (Netherlands)

ROR

<https://ror.org/02nwyam20>

Funder(s)

Funder type

Industry

Funder Name

Stryker European Operations BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration