ISRCTN17022568 https://doi.org/10.1186/ISRCTN17022568

Stryker NTX registry

Submission date	Recruitment status	[ ] Prospectively registered
21/01/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/03/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2021	Musculoskeletal Diseases	[ ] 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?
Britta von den Brincken, britta.vondenbrincken@stryker.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02525562

Secondary identifying numbers
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 dEich, Luxembourg: CNER (Comité National dEthique de Recherche), 14/09/2011, ref: #201109/01
2. Maria Middelares, Belgium: AZ Maria Middelares 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: Arztekammer 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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/06/2012

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

Age group
Adult

Sex
Both

Target number of participants
1600

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
England

Germany

Luxembourg

United Kingdom

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)

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Sponsor type
Industry

Website
http://www.stryker.com/

ROR
https://ror.org/02nwyam20

Funder(s)

Funder type
Industry

Funder Name
Stryker European Operations BV (Netherlands)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-review journal

Intention to publish date
01/07/2022

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration