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Scorpio knee prosthesis following the Lazirush concept versus Scorpio knee prosthesis following the joint care concept

Submission date
14/06/2013

Recruitment status
No longer recruiting

Registration date
06/08/2013

Overall study status
Completed

Last Edited
18/01/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A new program aiming to improve a fast comfortable recovery after total knee replacement is called the Lazirush concept or the 2-day Knee. By not using pain pumps, drains or catheters the risk for infection will be minimized. Also during the operation no tourniquet (bandage) will be used, which will reduce bleeding and swelling after surgery thereby leading to a possible faster activation of muscle function and performance. The inventor of the procedure, Dr Gijzelings (AZ Alma, Eeklo, Belgium) has 10 years of clinical experience with the Lazirush concept. Reports of the patient outcome have been very successful showing improved short-term functional outcome.
The aim of the study is to evaluate the early and late postoperative results of the Scorpio knee prosthesis following the Lazirush concept and compare this with a group of patients undergoing a Scorpio knee prosthesis following the Joint Care concept.

Who can take participate?
Patients requiring a total knee replacement.

What does the study involve?
Patients are randomly allocated to either group A or group B.
Group A: 25 patients undergoing total knee replacement, operated and treated by the traditional Joint Care concept
Group B: 25 patients undergoing total knee replacement, operated and treated by the Lazirush concept
Patients are then followed until 12 weeks after surgery. Usual clinical data will be collected and particularly quality of life will be assessed.

What are the possible benefits and risks of participating?
Information obtained from this study may increase the knowledge about the Lazirush and Joint Care concept in total knee replacement.

The study involves the routine assessment of a knee replacement procedure. The devices are CE marked and will be used according to their labelling. At 6 weeks one additional long leg X-ray will be taken. The additional radiation dose is negligible and will do the patient no harm.

Where is the study run from?
Medisch Centrum Alkmaar, Netherlands.

When is the study starting and how long is it expected to run for?
The study will run from May 2011 to December 2012.

Who is funding the study?
Stryker

Who is the main contact?
Eric Garling, Stryker

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
K-S-029

Study information

Scientific Title
Feasibility study to evaluate the clinical outcome of the Scorpio knee prosthesis following the Lazirush concept

Study objectives
To evaluate the early and late postoperative results measured by the knee society score (KSS) and range of motion (ROM) of the Scorpio knee prosthesis following the Lazirush concept and compare this with a group of patients undergoing a Scorpio knee prosthesis following the Joint Care concept.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee (METC) North Holland (Medisch Ethische Toetsingscommissie Noord-Holland); 7 April 2011; kenmerk:NH011.154, METC-registratie M010-043, CCMO-registratie:NL33089.094.10

Study design
Single centre randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary unilateral total knee replacement

Interventions
The patients who are willing to participate in this study and who signed an informed consent are randomly assigned to group A or group B.
Group A: 25 patients with total knee arthroplasty (TKA), operated and treated by the traditional joint care concept
Group B: 25 patients with TKA, operated and treated by the Lazirush concept

Patients are then followed until 12 weeks after surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
In this feasibility study for a multi center study the primary objective is to evaluate the early and late postoperative results measured by the Knee Society Score (KSS) and Range of Motion (ROM) of the Scorpio knee prosthesis following the Lazirush concept and compare this with a matched group of patients undergoing a Scorpio knee prosthesis following the Joint Care concept. The data of the range of motion measurements and the KSS will be analyzed with parametrical statistical techniques, such as t-tests, unless the normality assumption does not seem reasonable for the data, in which case non-parametric techniques will be considered e.g. Wilcoxon/Mann-Whitney tests. All data will be analyzed by blinded researchers. KSS is measured at pre-operative visit and then at Week 2, 6 and 12 after surgery. ROM is measured at pre-operative visit and then at Day 1, 2, 3, 4, 5, 6, 7, and Week 2, 6 and 12 after surgery.

Key secondary outcome(s))
The secondary outcomes evaluate the early and late postoperative results concerning the incidence and type of postoperative averse events, duration of hospital stay, use of pain medication, need for blood transfusion, HB level, drain production, operation parameters, knee swelling, Knee injury and Osteoarthritis Outcome Score (KOOS), Straight leg raise, ambulatory status, single leg stance, ability to walk stairs, X-ray parameters, patient satisfaction, need for

home care, resumption of work, chair rise ability, walking speed, amount of pain during rest and activity, and economical costs of the Scorpio knee prosthesis following the Lazirush concept and compare this with a matched group of patients undergoing a Scorpio knee prosthesis following the Joint Care concept. Concerning the secondary outcome measures a difference will be made between continuous outcome variables and categorical outcome variables. Continuous outcome variables and their differences will be analysed with parametrical statistical techniques, such as t-tests, unless the normality assumption does not seem reasonable for the data, in which case non-parametric techniques will be considered e.g. Wilcoxon/Mann-Whitney tests. Categorical outcome variables will be analysed with chi-square tests and/or Fisher's exact tests (depending on the expected values in the categories). For the relevant parameters (e.g. pain and function) also the 95 percent confidence intervals will be calculated. The effect of parameters such as age, sex will be evaluated using multiple variate analysis. All data will be analysed by blinded researchers.
All these secondary outcomes are measured at pre-operative visit and then at week 2, 6 and 12 after surgery. For some outcomes, they will also be measured at day 1, 2, 3, 4, 5, 6, 7 after surgery.

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients willing to sign the informed patient consent form.
2. Patients willing and able to comply with scheduled postoperative clinical and radiographic evaluations and rehabilitation.
3. Patients requiring a primary unilateral total knee replacement.
4. Patients with American Society of Anesthesiologists (ASA) Physical status 1 & 2.
5. Patients having a partner at home for assistance.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with Rheumatoid arthritis, insulin-dependent diabetes, severe osteoporosis, or an inflammatory cause for osteoarthritis.
2. Patients with other lower limb problems than their planned primary unilateral total knee arthroplasty.
3. Patients requiring revision knee surgery.
4. Patients with ASA physical status more than 2.
5. Patients requiring bilateral total knee replacement.

Date of first enrolment
01/05/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Stryker Nederland BV
Waardenburg
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Sponsor information

Organisation
Stryker SA (Switzerland)

ROR
https://ror.org/04t7jet59

Funder(s)

Funder type
Industry

Funder Name
Stryker SA (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan
Only aggregated data will be included included in the results publication to ensure no GDPR breaches.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018	17/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes