Flexible versus standard intramedullary rod in Triathlon primary total knee replacement: effects on sagittal contour of the distal femur, implant positioning, functional outcome and sizing

Published: 30-03-2015
Last updated: 15-05-2024

We expect that the use of the flexible IM rod results in a post-operative sagittal contour of the distal femur that resembles the pre-operative situation, i.e. a better fit of the prosthesis, when compared to the use of the the standard IM rod

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

Summary

ID

NL-OMON29107

Source
Nationaal Trial Register

Brief title
FLIRT-1

Condition

- Joint disorders

Synonym
Artrose - totale knieprothese

Health condition

Osteoartritis - Total knee arthroplasty

Research involving
Human

Sponsors and support

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

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

The contour of the distal femur is quantified in (first): the flexion angle of the TKA in the sagittal plane.

Secondary outcome

1. The contour of the distal femur is also quantified in the sagittal profile: anterior and posterior.

2. Functional outcome measured with:

o Get up and Go test

o Stair climbing test

o Knee power output

Study description

Background summary

Total knee arthroplasty (TKA) is a cost-effective surgical procedure for degenerative knee disease. TKA has good long-term results (Gill OS 1999). However, these results are not always related to patient satisfaction and functional outcome (Anderson JG 1996). This may be caused by the fact that the dynamics of the TKA do not properly mimic the dynamics of

the natural knee. Manufacturers of TKA's have addressed this by integrating aspects of natural knee dynamics into their models.

The Triathlon primary TKA is a single-radius of curvature implant, mimicking a single flexion/extension axis located in the distal femur. It is hypothesised that the single-radius concept yields better function, and that it results in enhanced efficiency of the extensor muscles. A recent 4-year follow-up study of the Triathlon TKA shows good results for pain and functional outcome (Hamilton DF 2013). Three models of the Triathlon are currently available: the Posterior Stabilized (PS), Cruciate Retaining (CR) and Cruciate Substituting (CS) knee replacement. All these models can be placed by either using the standard intramedullary (IM) rod or the newer flexible intramedullary rod.

Up till now, the literature has not been conclusive whether the orthopaedic surgeon should use one of both options and acknowledges the dilemma of implanting the femoral component either according to the anatomy of the distal femur, or according to the longitudinal axis of the femur in the sagittal plane, thus ignoring the sagittal bowing (Yehyawi TM 2007). The first option (following distal anatomy) should result into a more flexed femoral component compared to a more extended femoral component. While the standard IM rod is still being considered a safe option, it is hypothesized that the advantage of the flexible rod is that, due to following the distal anatomy, less bone needs to be removed and that the femoral component has a proper fit to the natural anatomy of the distal femur in the sagittal plane. Together with the single radius concept of the Triathlon, this would lead to more natural femorotibial kinematics and, eventually, to better functional outcome.

The goal of this study is to compare the flexible IM rod to the standard IM rod in Triathlon primary TKA in terms of fit of the TKA and functional outcome. This comparison will help in the search for the optimal surgical technique in combination with a knee implant that mimics natural joint motion and feels best for the patient.

Study objective

We expect that the use of the flexible IM rod results in a post-operative sagittal contour of the distal femur that resembles the pre-operative situation, i.e. a better fit of the prosthesis, when compared to the use of the the standard IM rod

Study design

The patients included in the study will be seen at several moments: pre-operative, operation/direct post-operative, and 3 months, 1 year and 2 years post-operative.

Intervention

Flexible intramedullary rod in combination with Triathlon posterior-stabilized total knee arthroplasty

Contacts

Public
Sint Maartenskliniek Nijmegen

Secretariaat Research
Hengstdal 3
6574 NA
Ubbergen
Nederland

024-3659140
Scientific
Sint Maartenskliniek Nijmegen

Secretariaat Research
Hengstdal 3
6574 NA
Ubbergen
Nederland

Nijmegen 6500 GM
The Netherlands
024-3659140

Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

• Patient with non-inflammatory knee osteoarthritis which is radiologically confirmed and which requires total knee replacement

• Age between 40 and 75 years, inclusive

• Patient plans to be available for follow-up until two years post-operative

• Patient is in stable health and is free of or treated for cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk

Exclusion criteria

• Patient has a BMI > 35

• Patient's expected physical activity after surgery is 2 or less on the UCLA Activity Scale

• Patient has had previous hip or knee replacement surgery in the last 6 months, or is planned to have a (second) hip or knee replacement in the next 6-12 months (because of the effect on function)

• Patient has had a previous hip replacement on the affected side (this may cause for a restriction for the rod placement during surgery)

• Patient has had major, non-arthroscopic surgery to the study knee, including HTO.

• Patient has an active, local infection or systemic infection

• Patient has physical, emotional or neurological conditions that would compromise compliance with post-operative rehabilitation and follow-up

• Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis

• Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function

• Severe instability of the knee joint due to loss of cartilage reported as “substance loss”

• Patient has knee flexion < 90 degrees

• Patient has fixed flexion deformity >10 degrees (passive extension lag)

• Patient has > 30 degrees extension deficit (active restraint to extension)

• Patient does not have a proper functioning patella tendon on the affected side; measured as inability of active extension of the knee

• Patient has quadriceps weakness on the affected side; score on MRC scale < 4

• Patient has rheumatoid arthritis, any auto-immune disorder or immunosuppressive disorder

Study design

Design

Study phase:	N/A
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2015
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	23-10-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

ID: 40562
Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4888
NTR-old	NTR5125
CCMO	NL46940.048.14
OMON	NL-OMON40562

Study results

Actual enrolment: 60

Summary results
N/A