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The effect of implant design on patient outcomes following total knee replacement

Submission date
24/02/2012

Recruitment status
No longer recruiting

Registration date
11/04/2012

Overall study status
Completed

Last Edited
14/11/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims:
Total knee replacement (TKR) is the established way to treat end-stage osteoarthritis of the knee (when other treatment modalities have been exhausted). Currently more than 50,000 knee replacements are implanted every year in the UK. Over the past 30 years many new versions of knee replacements have been introduced with the development of technology supposedly leading to improvement in the function of the implant and hence the outcome for the patient. In current orthopaedic practice several different versions of TKR are in common use in the UK, and outcome studies using knee pain and functional scoring systems show similar results for most types of implants - around 90% survivorship at 10 years and generally good functional results. The aim of this study is to compare the outcome of a new type of knee replacement implant (Triathlon) which, it is claimed, allows greater movement of the knee and better function for patients than the current standard knee replacement implant (Kinemax). Both implants have received approval from the National Authorities and are currently used in this hospital. The surgeons involved in this study are experienced in using both types of knee replacement but it is not known whether one gives better results for patients.

Who can participate?
Patients with osteoarthritis on the waiting list for primary TKR

What does the study involve?
Participants are randomly allocated to receive one of the two implants (either Kinemax or Triathlon). All other aspects of the operation and post-operative care are the same as for those not taking part in this study. There is no technical difference in the surgery and no difference in the nursing care or rehabilitation. Participants are assessed at the pre-admission clinic visit (about 2 weeks before the surgery) and at 6 weeks, 6 months and then at 1, 3 and 5 years after the operation. The assessor does not know which type of knee has been used. Assessments involve questionnaires on issues such as the knee pain and stiffness, general health and daily activities. Knee movement, leg strength and ability to undertake some simple day to day tasks, such as walking up and down stairs, getting up from a chair and walking a measured distance, are all measured.

What are the possible benefits and risks of participating?
There should be no additional harmful effects caused by participation in this study in addition to those for people undergoing knee replacement surgery. Both types of implants have been routinely used. During the assessments participants are asked to perform normal activities of daily life such as climbing stairs which may cause some knee pain. However, they are asked to perform those activities in the same way as they would usually do, minimising the pain as much as possible. Participants can always at any moment withdraw from the tests. It is hoped that either treatment will help with pain and dysfunction. Both implants have been approved for use in the UK, but it is not known which implant will help the most and this is why this study is taking place. The information will help to plan treatment for future patients with osteoarthritis requiring a knee implant.

Where is the study run from?
University of Edinburgh and NHS Lothian. All operations and follow-up clinics will be carried out via the Royal Infirmary of Edinburgh (UK)

When is the study starting and how long is it expected to run for?
February 2008 to October 2015

Who is funding the study?
Styrker Orthopaedics (UK)

Who is the main contact?
Dr David Hamilton
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TRIMAX.v2

Study information

Scientific Title
Comparison of outcome in Total Knee Replacement (TKR) using a new design 'single-raduis-of-curvature' implant (TRIathlon) versus a traditional design 'multi-raduis' implant (KineMAX)

Acronym
TRIMAX

Study objectives
That a new implant designed based on modern kinematic theory of the knee would demonstrate enhanced functional outcome in comparison to a traditional design of knee prosthesis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Local Research Ethics Committee, 04/12/2006, ref: 06/S1103/50

Study design
Single-centre prospective double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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 / total knee arthroplasty

Interventions
Primary total knee arthroplasty - Patients randomised to either Triathlon or Kinemax implants

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Change in Oxford Knee Score
2. Lower limb extensor mechanism power output (Leg Extensor Power Rig)
Measured pre-op, 6 weeks, 6 months, 12 months, 3 years and 5 years

Secondary outcome measures
1. Knee range of movement (flexion/extension)
2. Battery of timed functional performance tests (timed up-and-go, stairs climb, 8 metre walk)
3. Pain scores (0-10 numerical rating scale)
4. Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index
Measured pre-op, 6 weeks, 6 months, 12 months, 3 years and 5 years

Overall study start date
25/02/2008

Completion date
30/10/2015

Eligibility

Key inclusion criteria
1. Diagnosis of osteoarthritis
2. Planned primary total knee arthroplasty with standard implants
3. Capacity to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
204 (102 patients per arm)

Key exclusion criteria
1. Inability to fulfill the inclusion criteria
2. Comorbidities that would affect post operative recovery or subsequent physical performance

Date of first enrolment
25/02/2008

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Royal Infirmary of Edinburgh
Edinburgh
United Kingdom
EH16 4SB

Sponsor information

Organisation
University of Edinburgh (UK)

Sponsor details
Queen's Medical Research Institute
47 Little France Crescent
Edinburgh
Scotland
United Kingdom
EH16 4JT

Sponsor type
University/education

Website
http://www.ed.ac.uk

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Industry

Funder Name
Stryker Orthopaedics (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015		Yes	No