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Validation of TKA Easy software: Are the clinical outcomes the same as the TKA 4.3 software?

Submission date
21/11/2011

Recruitment status
No longer recruiting

Registration date
18/06/2012

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
The research aims to validate a new computer application for use during computer-assisted total knee replacement. The aim of the study is to show that the clinical outcomes when using this software are the same or better when compared to those using the older version of the software. The new software has been designed to be easier to use and has a more simple 'work flow' (the steps the surgeon has to go through when using the software) and so is expected to take less time than the older version. Consequently we will also investigate whether the use of the new software results in a shorter operation time when compared to the older version.

Who can participate?
All patients under the care of Mr F. Picard and Mr D. Allen who are coming in for a total knee replacement within our institution (Golden Jubilee National Hospital).

What does the study involve?
The patients will be randomly allocated to either the OrthoPilot TKA easy application or to the former version of navigation software (TKA 4.3). The study involves the patient's own treatment and all patients will have their operation done by their consultant. The exception to this is that at the six weeks review they will have a Computerised Tomography (CT) scan of the knee (using the Imperial knee protocol) instead of the routine hip-knee-ankle X-ray to determine the alignment of the prosthesis.

What are the possible benefits and risks of participating?
By taking part in this study the patient will be exposed to a slightly increased dose of radiation than would otherwise be the case. This is due to the patient having a CT scan instead of a long-length x-ray to assess the position of the knee replacement. However, we will be using a CT protocol that reduces the radiation you receive. The dose has been calculated by our radiation protection advisor and has been classified as a minor risk. The ethics committee is happy with this radiation level. We cannot promise that the patient will directly benefit from the study but the information we get from this study may help in the treatment of other people having computerised navigated total knee replacement.

Where is the study run from?
The study is taking place at the Golden jubilee National Hospital, Clydebank

When is the study starting and how long is it expected to run for?
The study started in February 2012. We are recruiting 220 patients and are hoping to have the number of patients required by August 2013.

Who is funding the study?
The study is funded by the National Waiting Times Centre Board, Golden Jubilee National Hospital, Clydebank. We have also received a fund from Aesculap Ag (Germany) who own the software.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Mr Frederic Picard

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11/ORTH/04

Study information

Scientific Title
Validation of TKA Easy software: Are the clinical outcomes the same as the TKA 4.3 software?: a randomised controlled study

Study objectives

1. To determine if the clinical, functional and radiological outcomes following implantation of a knee using the Orthopilot Total Knee Arthroplasty (TKA) easy software are the same as those following implantation of a knee using the Orthopilot TKA 4.3 software.
2. To determine whether there is a decrease in the registration time and hence the operative time when using OrthoPilot TKA easy application when compared to a former version of navigation software (TKA 4.3).

On 01/07/2015 the overall trial end date was changed from 28/02/2013 to 26/11/2013.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 5, 17/01/2012, Ethics No: IRAS: 88263/269718/1/891, REC No: 11/WS/0125.

Due to a prior advice by our R&D department, we had put the application on hold as we were advised we do not need to register the trial since it's a non-drug trial and software and implants are CE marked. So first patient was recruited on 08/02/2012.

Study design
Randomised single-blinded controlled study in a single centre

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Navigated Total Knee Arthroplasty

Interventions
All patients will undergo a primary navigated TKA.

Patients will be assessed at the pre-operative clinic, and an Oxford Knee Score will also be taken as part of their routine clinical care. The study will be discussed. Following consent the patient will be randomised using sequentially numbered, opaque sealed envelopes (SNOSE) 8. The research coordinator (or nominated person) who will be independent of the approach and consent of the patients to the study will name, sign and open the envelope and inform the study

team of the randomisation. One group (Easy) will be randomised to the OrthoPilot TKA easy application. The second group (4.3) will be randomised to the former version of navigation software (TKA 4.3).

The patient will then undergo a navigated TKA as normal. The prosthesis used will be the Columbus knee prosthesis which is normally used by both surgeons in the study. This prosthesis holds a CE certification and is a class III medical product. Passive trackers will be used in both treatment groups irrespective of the software being used. In both cases the standard software will be used. This will exclude use of the software that allows for a soft tissue balancing procedure. The registration time will be automatically recorded by the software. The total operation time will be defined as the 'skin to skin' time and will be recorded by an independent theatre person who is not involved in the study. The surgeon will not be made aware of the operation time until the end of the surgery to decrease the risk of bias. For this purpose theatre clocks will be covered.

The patient will be seen post-operatively during their inpatient stay and followed-up at six weeks. At six weeks they will have a Computerised Tomography (CT) scan of the knee (using the Imperial knee protocol) instead of the routine hip-knee-ankle X-ray to determine the alignment of the prosthesis. The total effective dose for this protocol has been calculated by the Radiation Protection Adviser and Consultant Medical Physicist (Dr A. G. Brennan) to be 0.6mSv which falls in the minor risk category for bio-medical research. Following an agreement with the local radiology department, patients will attend for their CT scan on a Monday, Tuesday or Thursday between the hours of 12 and 2.00pm. Patients will be informed of this restriction to their follow up time in the patient information sheet. The radiological outcomes will be assessed by a radiologist independent to the study. The patients will also have a routine post-operative assessment with our Arthoplasty clinic where the Oxford Knee Score, patient satisfaction and range of motion (ROM) will be recorded as per local policy. The ROM will be recorded using an electronic goniometer. In addition to these routine scores, the Knee Society Score will also be recorded.

It is expected that the recruitment time will be nine months.

The data that will be collected and analysed will be demographic data [gender, age at operation, Society of Anesthesiologists physical status score (ASA), BMI, etiology and pre-operative knee oxford score], type of knee (varus/valgus knee, range of movement [ROM], degree of fixed flexion if present, Kellgren Lawerence Score and Ahlback Classification), operative details (date of TKA, side, registration and operative time), clinical outcome (ROM and re-admission rate due to complications such as wound problems, infection, pain and deep vein thrombosis (DVT) /pulmonary embolism (PE), patient satisfaction, post-operative Oxford knee score, Knee Society Score (KSS) and radiological outcome using CT scan (radiolucency according to zone, rotational alignment, coronal mechanical femoral axis, sagittal mechanical femoral axis, coronal mechanical tibial axis, sagittal mechanical tibial axis, coronal femorotibial angles). The number of outliers beyond +/- 3° will then be calculated for each group.

The research team will not be blinded to the allocation of patients to each group. However the independent radiologist who will assess the CT-scans will be, as will the arthroplasty practitioners who will collect the patient satisfaction, ROM and Oxford score post-operatively.

Intervention Type
Procedure/Surgery

Primary outcome measure

The overall lower limb coronal alignment (mechanical femorotibial angle) as measured on the post-operative CT scan

Secondary outcome measures
1. Radiological - Component alignment and rotation and sagittal lower limb alignment
2. Patient reported outcome measures - Oxford knee score and Patient Satisifaction
3. Clinical outcomes - Knee Society Score, range of motion, number of complications
4. Operative times - registration time and overall operative time

Overall study start date
01/02/2012

Completion date
26/11/2013

Eligibility

Key inclusion criteria
1. Patients having a primary navigated knee arthroplasty
2. Able to give informed consent
3. Able to return for follow-up

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Patients with a body mass index (BMI) > 40
2. Patients who are known pre-operatively to require patellar resurfacing
3. Patients who do not wish to participate
4. Patients who are unable to give informed consent
5. Patients who are unable to attend for follow up

Date of first enrolment
08/02/2012

Date of final enrolment
07/10/2013

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Golden Jubilee National Hospital
Clydebank
United Kingdom
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Sponsor information

Organisation
National Waiting times Centre Board (UK)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0103jbm17

Funder(s)

Funder type
Industry

Funder Name
Aesculap Ag (Germany)

Funder Name

National Waiting Times Centre Board, Golden Jubilee National Hospital (UK)

Results and Publications

Publication and dissemination plan
Full manuscript to be submitted to peer-reviewed journal by August 2015

Intention to publish date
01/08/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/10/2016	18/01/2019	Yes	No