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All ligaments left In knee arthroplasty trial

Submission date
10/07/2017

Recruitment status
No longer recruiting

Registration date
14/07/2017

Overall study status
Completed

Last Edited
19/01/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Knee osteoarthritis (OA) occurs when the protective cartilage on the end of bones wears away. The bones in the knee then rub against one another, causing stiffness, pain and a reduction in the range of movement. Knee replacement surgery is a common treatment for osteoarthritis of the knee. There are different types of knee replacement systems, or 'implants', that can be used in the surgery. Current research looking at changes to these implants are limited. Research is needed to consider the changing characteristics of the patients who require knee surgery. Currently there is an increase in demand for knee replacement in a younger and more active population, who desire less limitation on their activities following knee replacement surgery. Current knee replacement designs sacrifice one of the main ligaments (a piece of tissue that connects the bones that hold together a joint) in the knee, called the Anterior Cruciate Ligament (ACL). By preserving natural knee structures, such as the ACL, it is thought that the knee will retain more normal function following surgery. The Vanguard CR is a commonly used knee replacement, and it sacrifices the ACL. Zimmer Biomet have developed a new knee replacement implant called the Vanguard XP which keeps all the main knee ligaments intact. This new design may benefit the younger, more active population. The aim of this study is to evaluate the early outcomes of the Vanguard XP compared to the Vanguard CR.

Who can participate?
Adults aged 18 and older who have osteoarthritis of the knee requiring surgery.

What does the study involve?
Participants are allocated to one of two groups. Those in the first group receive the Vanguard CR during their knee replacement surgery. Those in the second group receive the Vanguard XP during their knee surgery. Participants are followed up six weeks after surgery and again one, two and three years post-surgery to evaluate their pain levels, the safety of the knee systems, quality of life and outcomes of their surgery.

What are the possible benefits and risks of participating?
There are no direct benefits with participating. There are risks associated with all types of surgery and anesthetics. Steps are taken to ensure these risks are minimised. The Vanguard XP system is the newer type of knee prostheiss however it has been approved for use in Europe and the FDA. There are risks with x-rays of exposure to radiation. However, the amount of exposure with this study is within the recommended guidelines.

Where is the study run from?
1. Nuffield Orthopaedic Centre (UK)
2. Frimley Park Hospital (UK)
3. Southmead Hospital (UK)
4. Royal Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2015 to February 2022 (updated 19/01/2021, previously: January 2021)

Who is funding the study?
Zimmer GmbH (Switzerland)

Who is the main contact?
Mrs Rachel Williams

Study website
https://www.ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/allikat

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03302013

Secondary identifying numbers
30729

Study information

Scientific Title
All Ligaments Left In Knee Arthroplasty Trial: Multi-center clinical study comparing the clinical and patient reported outcomes of the vanguard XP knee system to the vanguard CR knee system

Acronym
ALLIKAT

Study objectives
There is a difference in clinical and patient reported outcomes between the Vanguard XP Knee System and the Vanguard CR Knee System.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Berkshire B Research Ethics Committee approval, 20/04/2016, ref: 16/SC/0158

Study design
Randomised; Both; Design type: Treatment, Device, Surgery, Cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Specialty: Musculoskeletal disorders, Primary sub-specialty: Elective Orthopaedic Surgery; UKCRC code/ Disease: Musculoskeletal/ Other joint disorders

Interventions
Participants are randomly allocated to one of two groups, determining if they receive the Vanguard CR or the Vanguard XP, using an online system (RRAMP). Those in group one receive the Vanguard CR, which is the standard care option and acts as the control arm. Those in group two receive the Vanguard XP, this is the experimental arm using a new bi-cruciate retaining surgical technique and knee replacement system to retain the Anterior Cruciate Ligament.

A small preference cohort group of 60 patients receiving the Vanguard XP Knee System are recruited alongside the randomised controlled group. This data is used to confirm the external validity of the randomised controlled group group and to contribute to the safety data for the British Orthopaedic Association’s Beyond Compliance Programme.

Participants are followed up six weeks after surgery, and again at one, two and three years post randomisation to evaluate their pain levels, quality of life, knee function and surgical outcomes.

Intervention Type
Other

Primary outcome measure
Outcomes of knee surgery are measured using the Oxford Knee Score (using the Activity & Participation Questionnaire (OKS-APQ)) at baseline and three years post randomisation.

Secondary outcome measures
1. Patient reported outcomes are measured using the Oxford Knee Score - Activity & Participation Questionnaire and Forgotten Joint Score at post-operation (within six weeks), one and two years post randomisation
2. Quality of life is measured using the EuroQol five dimensions questionnaire (EQ-5D-3L) at post-operation (within six weeks), one, two, and three years post randomisation
3. Safety of Vanguard XP Knee System is measured using serious adverse events and complications at post-operation (within six weeks), one, two, and three years post randomisation
4. Clinical/functional assessment is measured using the American Knee Society Score at post-operation (within six weeks) and one and three years post randomisation
5. Beyond Compliance Programme is measured using Forgotten Joint Score at post-operation (within six weeks), one, two, and three years post randomisation
6. Radiographic Assessment (Alignment, Radiolucency, Loosening, Fixation/Migration) is measured using X-rays at one and three years post randomisation

Overall study start date
01/04/2015

Completion date
19/02/2022

Eligibility

Key inclusion criteria
1. Primary Osteoarthritis of the knee involving one or more compartments of the joint
2. Intact Anterior and Posterior Cruciate Ligaments
3. Intact collateral ligaments
4. Correctable coronal deformity
5. No more than 15 degrees of fixed flexion deformity

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 260; UK Sample Size: 260

Total final enrolment
77

Key exclusion criteria
1. Age under 18 years.
2. Revision knee replacement surgery
3. Rheumatoid Arthritis
4. Traumatic aetiology
5. History or clinical signs of ACL rupture
6. Previous arthroscopy related to ACL injury or reconstruction.
7. Correction of a flexion contracture that may require extensive resection of distal femur
8. Altered pain perception and / or neurologic affection due to diabetes.
9. Contraindications for the knee implant:
9.1. Cementless application of components*
9.2. BMI ≥40 kg/m2 *
9.3. Use of Anterior Stabilized Bearings*
9.4. Patients with severe pre-operative varus or valgus deformity ≥ 15 degrees*
9.5. Correction or revision of previous joint replacement procedure on index knee*
9.6. Infection
9.7. Sepsis
9.8. Osteomyelitis
9.9. Osteoporosis (requiring treatment)
10. Relative contraindications include:
10.1. Unco-
operative patient or patient with neurologic disorders who is incapable of following directions
10.2. Osteoporosis
10.3. Metabolic disorders which may impair bone formation,
10.4. Osteomalacia
10.5. Distant foci of infections which may spread to the implant site
10.6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
10.7. Vascular insufficiency, muscular atrophy, neuromuscular disease
10.8.
Incomplete or deficient soft tissue surrounding the knee, including the anterior cruciate ligament*

Date of first enrolment
05/09/2016

Date of final enrolment
04/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

Study participating centre
Frimley Park Hospital
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GU16 7UJ

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Westbury-on-Trym
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United Kingdom
BS10 5NB

Study participating centre
Royal Orthopaedic Hospital
The Royal Orthopaedic Hospital NHS Foundation Trust
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Sponsor information

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Sponsor type
University/education

Website
https://www.admin.ox.ac.uk/researchsupport/ctrg/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Zimmer GmbH

Results and Publications

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

Intention to publish date
19/06/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No