

All ligaments left In knee arthroplasty trial

Submission date 10/07/2017	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 14/07/2017	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/01/2021	Condition category Musculoskeletal Diseases	☐ 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 prosthesis 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

Contact information

Type(s)

Public

Contact name

Mrs Rachel Williams

Contact details

SITU

University of Oxford

Nuffield Orthopaedic Centre

Windmill Road

Headington

Oxford

United Kingdom

OX3 7LD

Additional identifiers

ClinicalTrials.gov (NCT)

NCT03302013

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Nuffield Orthopaedic Centre

Windmill Road
Headington
Oxford
United Kingdom
OX3 7LD

Study participating centre

Frimley Park Hospital

Frimley Health NHS Foundation Trust
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

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

Study participating centre
Royal Orthopaedic Hospital
The Royal Orthopaedic Hospital NHS Foundation Trust
Bristol Road South
Birmingham
United Kingdom
B31 2AP

Sponsor information

Organisation
University of Oxford

ROR
<https://ror.org/052gg0110>

Funder(s)

Funder type
Government

Funder Name
Zimmer GmbH

Results and Publications

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes