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Comparison of the JOURNEY II Bi-Cruciate Stabilised and GENESIS II Total Knee Arthroplasty in Performance and functional ABILITY: a randomised controlled trial

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
12/12/2017

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

Osteoarthritis causes the joints to become painful and stiff. Osteoarthritis of the knee is a common condition that is expected to be a lot more frequent in the next two decades. As a consequence, an increase of total knee replacement surgery is predicted. Total knee replacement surgery is offered when knee pain and stiffness caused by osteoarthritis can no longer be managed and these symptoms significantly impact on an individual's normal activities of daily living. Most total knee replacements are successful but up to 34% of all patients have poor functional outcomes following surgery. This leaves affected people at a greater risk of reduced physical activity and thus impacts longer-term general health. Poor outcomes are therefore of importance to patients and have a considerable financial and service-provision impact on NHS care. While patient-related characteristics and their relationship to patient outcomes have been identified, few studies have been undertaken to determine how kinematic outcomes (how the prosthetic knee moves) are related to functional outcome and patient satisfaction. The kinematic outcome of a total knee replacement is hypothesised to relate to both the structural design (shape) of the implant and the surgical procedure itself. To date, no studies have investigated the kinematic outcomes of different total knee replacement prosthesis designs through a range of typical activities of everyday mobility (functional outcomes). Whilst it is known that long term success of total knee replacement depends largely upon correct alignment of the prosthesis components during surgery, no studies have looked at the anatomical alignments of the osteoarthritic knee prior to undergoing surgery (using Computerised Tomography (CT) scanning).

The aim of the study is to examine relationships between movement analysis (kinematic and functional outcomes), patient reported outcome measures (PROMS) and CT measurement, both pre- and post-operatively, between two knee prosthesis including one that has been designed to improve functional outcomes.

Who can participate?

Adults aged 18 and older with primary osteoarthritis requiring a total knee replacement.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the GENESIS II knee prosthesis and those in the second group receive the JOURNEY II Bi Cruciate Stabilised (BCS). All participants undergo a CT scan both before and after surgery. Participants are asked to visit the movement laboratory at the University of East Anglia to complete tests to assess their range of movement, balance, walking ability and muscle activity before and after surgery. Participants answer questions about their pain medication they are taking, how they are coping with their knee before surgery and at one week, six-eight weeks and six months after surgery. Participants also complete a diary recording the daily exercises done at home after surgery as recommended by the participant's physiotherapists.

What are the possible benefits and risks of participating?
Although there are no direct benefits for participating, it is hoped that the information from this study will help improve the treatment of people undergoing knee replacement surgery in the future. Both the knee joints which we are testing are commonly used in Knee Replacement Surgery in the UK and there should be no additional risks in undergoing the surgery compared to patients who are not taking part in the study. Tests are carried out in the MoveEx Lab routinely. They involve no more than a participant's usual level of physical activity. These tests are well tolerated and do not involve any discomfort. However, if at any time during the assessment a participant does not want to continue, the tests would be stopped immediately. The CT scans are extra radiographic procedures compared to what a patient would have if they did not take part in the study. These procedures use ionising radiation and thus carry a small risk from the extra radiation that participants will be exposed to in the study. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chance of this happening to the participants within this study is extremely small due to the area of the body scanned and the small dose of radiation used. The ionising radiation dose used in this study (CT scans) is equivalent to that received, on average in the UK, from natural sources of background radiation in less than one year (10.5 months). This is estimated to correspond to a cancer risk of around 1 in 10,000 for adults in the general population. Sometimes, unexpected findings can be discovered on CT scans and we request the participants' permission to inform their GPs about these.

Where is the study run from?
This study is being run by the University of East Anglia (MoveEx Lab) (UK) and the Norfolk and Norwich University Hospital (NNUH) NHS trust (UK) with some participants being referred to the Spire Norwich Hospital (UK) for surgery and physiotherapy rehabilitation.

When is the study starting and how long is it expected to run for?
December 2016 to June 2021

Who is funding the study?
Smith and Nephew (UK), the manufacturer of both the total knee prosthesis used. However, this study is an investigator initiated study which means that the funder doesn't have any input in the design and the running of the study.

Who is the main contact?
Professor Iain McNamara (Scientific – Clinical), iain.mcnamara@nnuh.nhs.uk

Previous contacts no longer working on the study:
Bronwen Harry (updated 29/11/2019, previously: Dr Estelle Payerne) (Public), capability.nctu@uea.ac.uk
Dr Celia Clarke (Scientific – Biomechanical), Celia.Clarke@uea.ac.uk

Study website
http://www.uea.ac.uk/capability/home

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34594

Study information

Scientific Title
Comparison of the JOURNEY II Bi-Cruciate Stabilised and GENESIS II Total Knee Arthroplasty in Performance and functional ABILITY: a multi-centre, assessor, nurse, physiotherapists and patient blinded, 2-arm randomised controlled trial

Acronym
CAPAbility

Study objectives

The principal objective of the study is to compare the change in patient reported outcome scores of the Journey II BCS and the GENESIS II knee from operation to 6 months post-operation. This study will also investigate the relationships between patient reported, clinical, kinematic and radiological outcomes for these two types of knee replacement joints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge Central Research Ethics Committee, 27/07/2017, ref: 17/EE/0230

Study design
Randomised; Both; Design type: Treatment, Device, Qualitative

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 of the knee joint

Interventions
Participant are randomly allocated to receive either the JOURNEY II Bi Cruciate Stabilised (BCS) or the GENESIS II total knee implant.
The JOURNEY II BCS knee implant (intervention) has been structurally designed to improve kinematic outcomes for patients
The GENESIS II knee (standard care) is the implant routinely used at the Norwich and Norfolk University Hospital NHS trust.

In both groups participants are asked to undertake a CT scan before and after surgery (at the Norfolk and Norwich University Hospital). Participants are asked to answer some questions, about the pain medication they are currently taking and how they are coping with their knee, before surgery and 1 week, 6-8 weeks and 6 months after. They then visit the movement laboratory (MoveEx Lab) at the University of East Anglia, to complete some tests to look at the current range of movement of their affected knee, before surgery and 6-8 weeks and 6 months after. At these visits the research team also take some measurements of the participants' balance, walking ability and muscle activity in their leg.
Participants are interviewed about their hopes and expectations for the surgery and how they

are managing pain, before surgery (at MoveEx Lab visit) and a week after (on the phone). Some participants will also be invited to take part in a further two interviews 6-8 weeks and 6 months after surgery.
They are also asked to complete a diary recording the daily exercises done at home after surgery as recommended by the participants' physiotherapists

The study team makes sure that the above assessments are scheduled at the most convenient dates and times for the participants.

Intervention Type
Procedure/Surgery

Primary outcome measure
Function and pain is measured using Oxford Knee Score (OKS) at six months

Secondary outcome measures
Current secondary outcome measures as of 29/11/2019:
Patient reported outcome measures
1. Function and pain is measured using the Oxford Knee Score (OKS) at1 week and 6-8 weeks post-operatively
2. Higher levels of activity and (social) participation is measured using the Oxford Knee Score Activity & Participation Questionnaire (OKS_APQ) at 1 week, 6-8 weeks and 6 months post-operatively
3. Quality of life is measured using EuroQol (EQ- 5D-5L) at 1 week, 6-8 weeks and 6 months post-operatively
4. The patient' ability to forget about a joint as a result of successful treatment is measured using the Forgotten Joint Score (FJS) at 6-8 weeks and 6 months post-operatively
5. Physical activity is measured using the UCLA activity score at 6-8 weeks and 6 months post-operatively

Clinical efficacy outcomes:
1. The clinical efficacy of the arthroplasty is assessed by measuring the Knee Flexion Range of Movement (ROM) on discharge (routine care) at 6-8 weeks and 6 months post-operatively
2. The clinical efficacy of the arthroplasty is assessed by measuring the Knee extension ROM on discharge (routine care) at 6-8 weeks and 6 months post-operatively
3. Evolution of post-operative knee pain is measured using Changes in pain medication at 1 week, 6-8 weeks and 6 months post-operatively
4. The clinical efficacy of the arthroplasty is assessed by collecting arthroplasty related complications during surgery, 1 week, 6-8 weeks and 6 months post-operatively
5. The clinical efficacy of the arthroplasty is assessed by collecting the rate of revision surgery at 1 week, 6-8 weeks and 6 months post-operatively
6. The clinical efficacy of the arthroplasty is assessed by measuring the timed Up and Go at 6-8 weeks and 6 months post-operatively
7. The clinical efficacy of the arthroplasty is assessed by measuring the timed 6 minute walk at 6-8 weeks and 6 months post-operatively
8. The clinical efficacy of the arthroplasty is assessed by collecting the Length of hospital stay, which is an indicator of clinical efficacy, is measured at discharge
9. The clinical efficacy of the arthroplasty is assessed by evaluating the routine post-operative plain radiographs against the pre-operative one to record any surgical error has taken place. This

will be undertaken by two consultants who had not conducted the surgery
10. The clinical efficacy of the arthroplasty will be assessed by determining the rotational profile of the implant position using pre- and post- operative rotational profile CT scan

Clinical safety outcomes:
The clinical safety of the surgery is assessed by collecting surgery related complications peri and post-operatively

Biomechanical Outcomes are measured using:
1. Overground walking is measured using 3D Motion analysis and EMG at baseline, 6-8 weeks and 6 months post-operatively
2. Stair climbing and descending is measured using 3D Motion analysis and EMG at baseline, 6-8 weeks and 6 months post-operatively
3. Static balance is measured using a force plate at baseline, 6-8 weeks and 6 months post-operatively
4. Dynamic balance is measured using a force plate and the modified Star Excursion Balance Test (mSEBT) at baseline, 6-8 weeks and 6 months post-operatively
5. Leg muscle strength measured using maximal voluntary isometric contraction (MVIC) test of the hamstring and quadriceps muscles on both limbs.

Radiological outcome:
1. Rotational alignment of the total knee component is assessed by measuring the femoral ante-torsion from the pre and post-operative rotational profile CT scans
2. Alignment of the total knee component is assessed by measuring the tibial tubercle-trochlear groove distance (TT-TG) from the pre-operative rotational profile CT scan. This assesses the displacement which affects the patella tracking
3. Correct rotational alignment of the total knee component is assessed by measuring the tibial torsion from the pre and post-operative rotational profile CT scans. This compares the position of the tibial component
4. Correct rotational alignment of the total knee component is assessed by measuring the femoral component version from the post-operative rotational profile CT scan. The allows comparison of the rotation of the pre and post operative scans to look for local rotational alignment problems
5. Correct rotational alignment of the total knee component is assessed by measuring the tibial component version from the post-operative rotational profile CT scan. This allows comparison of the tibial component compared to the preoperative scans

Qualitative study:
1. Patient's perspective is assessed from semi-structured interviews undertaken at baseline and 1 week post-operatively for all participants and at 6—8 weeks and 6 months post-operatively for a purposive subsample
2. Surgeon's perspective is assessed from interviews undertaken at the end of the surgical aspects of the trial

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Previous secondary outcome measures as of 22/02/2019:
Patient reported outcome measures
1. Function and pain is measured using the Oxford Knee Score (OKS) at1 week and 6-8 weeks post-operatively
2. Higher levels of activity and (social) participation is measured using the Oxford Knee Score Activity & Participation Questionnaire (OKS_APQ) at 1 week, 6-8 weeks and 6 months post-operatively
3. Quality of life is measured using EuroQol (EQ- 5D-5L) at 1 week, 6-8 weeks and 6 months post-

operatively
4. The patient' ability to forget about a joint as a result of successful treatment is measured using the Forgotten Joint Score (FJS) at 6-8 weeks and 6 months post-operatively
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Overall study start date
08/12/2016

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Listed for a primary total knee replacement (TKR) at the Norfolk and Norwich University Hospital (may be referred to Spire Norwich for the operation to take place)
2. Indication for the TKR is primary osteoarthritis of the knee joint involving one or more compartments

3. Aged 18 or over
4. Patient willing to provide full informed consent to the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
81

Key exclusion criteria
Current exclusion criteria as of 22/02/2019:
1. Listed for a single-stage bilateral TKR procedure
2. Severe symptoms in the contralateral knee so as to require staged bilateral knee replacements within 6 months of the primary procedure
3. Fixed flexion deformity of 15 degrees or greater who will require excessive resection of the distal femur
4. Clinically assessed uncorrectable varus/valgus deformity of 15 degrees or greater
5. Any co-morbidity which, in the opinion of the investigator, is severe enough to present an unacceptable risk to the patient's safety
6. Inflammatory arthritis
7. Previous septic arthritis in the affected knee joint
8. Previous surgery to the collateral ligaments of the affected knee
9. A contralateral total knee replacement that has been implanted less than one year from the date of consultation
10. A contralateral total knee replacement that is severely painful
11. Patients on warfarin or novel oral anticoagulants (NOACs)
12. Will not be resident in the catchment area for NNUH for at least 6 months post-surgery
13. Undertaking the surgery as a private patient
14. Patients who, in the opinion of the clinical staff, do not have capacity to consent
15. Patients who are pregnant
16. Unable to understand written and spoken English

Previous exclusion criteria:
1. Listed for a single-stage bilateral TKR procedure
2. Severe symptoms in the contralateral knee so as to require staged bilateral knee replacements within 6 months of the primary procedure
3. BMI greater than 35
4. Fixed flexion deformity of 15 degrees or greater who will require excessive resection of the distal femur

5. Clinically assessed uncorrectable varus/valgus deformity of 15 degrees or greater
6. Any co-morbidity which, in the opinion of the investigator, is severe enough to present an unacceptable risk to the patient's safety
7. Inflammatory arthritis
8. Previous septic arthritis
9. Previous knee surgery other than diagnostic arthroscopy or menisectomy
10. Patients on warfarin
11. Will not be resident in the catchment area for NNUH for at least 6 months post-surgery
12. Undertaking the surgery as a private patient
13. Patients who, in the opinion of the clinical staff, do not have capacity to consent
14. Patients who are pregnant
15. Unable to understand written and spoken English

Date of first enrolment
05/07/2018

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Spire Norwich Hospital
Old Watton Road
Colney
Norwich
United Kingdom
NR4 7TD

Study participating centre
MoveEx lab
School of Health Sciences

University of East Anglia
Earlham Road
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
Norfolk and Norwich University Hospitals NHS Foundation Trust

Sponsor details
Colney Lane
Colney
Norwich
England
United Kingdom
NR4 7UY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Industry

Funder Name
Smith & Nephew Medical Limited

Results and Publications

Publication and dissemination plan
1. The results of the trial will be disseminated regardless of the direction of effect and will be reported following the Consolidated Standards of Reporting Trials (CONSORT) Statement. The publication policy will be in line with rules of the International Committee of Medical Journal Editors

2. The data is planned to be published in a high-impact peer reviewed journal
3. The TMG will decide on the dissemination strategy including presentations, publications and authorship

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
Requests for access to individual participant data will be considered by the Chief Investigators. Requests can be made to dm.norwichctu@uea.ac.uk. The trial protocol and Statistical Analysis Plan (SAP) will also be made available as supplementary files.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/02/2020	26/02/2020	Yes	No
Results article		04/01/2023	06/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		25/11/2021	31/01/2025	Yes	No