Randomised controlled trial to compare the functional outcome of the standard NexGen Legacy knee replacement to that of the NexGen Legacy Flex knee replacement which is designed to allow a greater range of flexion in the knee

Submission date	Recruitment status	Prospectively registered
13/10/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
04/12/2006	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
27/06/2008	Surgery	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Z0002

Study information

Scientific Title

Study objectives

Does the use of the NexGen Legacy Flex knee replacement produce significantly better outcomes than those obtained with the standard NexGen Legacy knee replacement?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Lothian Research Ethics Committee on 17/2/2004 (ref: LREC2003 /1/36).

Study design

Prospective, double blind, randomised controlled trial.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Total knee replacement surgery in patients with osteoarthritis

Interventions

Standard NexGen Legacy knee replacement versus the NexGen Legacy Flex knee replacement

Intervention Type

Procedure/Surgery

Phase

Primary outcome measure

Functional range of movement of the knee using flexible electrogoniometry

Secondary outcome measures

- 1. Passive range of motion
- 2. Pain
- 3. Knee extensor and flexor strength
- 4. Walking speed
- 5. Woman on the Move Against Cancer (WOMAC)
- 6. Knee Society Score
- 7. Daily Physical Activity
- 8. Quality of Life

Overall study start date

01/03/2004

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients with knee osteoarthritis who are on the waiting list to undergo unilateral total knee arthroplasty at the New Royal Infirmary in Edinburgh and who can passively flex their knee 90 degrees or more.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

80, 40 in each group

Key exclusion criteria

- 1. Inflammatory polyarthritis
- 2. Disorders of the feet, hips or spine causing abnormal gait or significant pain
- 3. Dementia
- 4. Severe visual impairment
- 5. Neurological conditions affecting movement
- 6. Inability to give informed consent

Date of first enrolment

01/03/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre School of Health Sciences

Edinburgh United Kingdom EH6 8HF

Sponsor information

Organisation

Queen Margaret University College (UK)

Sponsor details

Clerwood Terrace Edinburgh Scotland United Kingdom EH12 8TS +44 (0)131 3173000 whardcastle@qmuc.ac.uk

Sponsor type

University/education

Website

http://www.qmuc.ac.uk

ROR

https://ror.org/002g3cb31

Funder(s)

Funder type

Industry

Funder Name

Zimmer UK Ltd (ref: Z0002)

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	01/01/2008		Yes	No