ISRCTN71676516 https://doi.org/10.1186/ISRCTN71676516

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Not Specified

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
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Sponsor information

Organisation
Queen Margaret University College (UK)

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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