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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**

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

### Study type(s)
Treatment

### 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(s)
Functional range of movement of the knee using flexible electrogoniometry

### Key secondary outcome(s))
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

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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
United Kingdom

Scotland

### Study participating centre

**School of Health Sciences**
Edinburgh
United Kingdom
EH6 8HF

# Sponsor information

**Organisation**
Queen Margaret University College (UK)

**ROR**
https://ror.org/002g3cb31

# Funder(s)

**Funder type**
Industry

**Funder Name**
Zimmer UK Ltd (ref: Z0002)

# Results and Publications

## 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 |