# Anteroposterior glide versus rotating platform low contact stress knee arthroplasty

Submission date	Recruitment status  No longer recruiting	Prospectively registered		
16/11/2006		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/01/2007	Completed	Results		
Last Edited	Condition category	Individual participant data		
17/08/2018	Musculoskeletal Diseases	Record updated in last year		

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Miss Katie Roebuck

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

Anteroposterior glide versus rotating platform low contact stress knee arthroplasty

### Study objectives

The Low Contact Stress (LCS) rotating platform Total Knee Arthroplasty (TKA) system attempts as near-normal reproduction of knee motion as possible, minimising interface stresses by allowing rotation (with this design, the posterior cruciate ligament has to be sacrificed). The AnteroPosterior (AP) glide LCS type allows both AP glide and rotation (with this design, the posterior cruciate ligament needs to be intact to allow normal femoral rollback). Rather than imposing a predetermined pattern of motion, the AP glide design permits bearing movement, which corresponds to the requirements of individual patient anatomy.

We hypothesise that these features of the AP glide type may allow improved joint position sense (proprioception) and better overall functional outcome. The LCS rotating platform design has good clinical results, but as results improve in terms of flexion and long term survival, more subtle measures of the return to near normal postoperative function become important. Proprioceptive function is affected by osteoarthritic process in knee joint. As it is one of the protective mechanisms, one should aim to preserve or enhance proprioception. Proprioceptive function after TKA is debated and there are conflicting results from various studies. Postoperative improvement depends on a number of factors including implant design and patient associated factors. To our knowledge there is no published study (literature search in Medline and National Research Register), which compares the results of AP glide and rotating platform design LCS knee arthroplasty. Therefore, we feel that a study in this subject is required.

We have conducted a pilot study (randomised controlled trial) to compare these two designs. 30 patients were randomly allocated either AP glide or rotating platform group. On the basis of data from the pilot study we have calculated that we need 44 patients (22 in each group) for the study. We have not made any changes at all in the methodology of the pilot study. After discussing with the team members involved in this study, it seems reasonable to include the patients from the pilot study. Hence we think that we need to recruit 20 more patients to complete the study.

## Ethics approval required

Old ethics approval format

#### Ethics approval(s)

North Staffordshire Local Research Ethics Committee - Favourable opinion received 19th October 2004.

#### Study design

A randomised controlled trial comparing the effects of AP glide and rotating platform design LCS knee arthroplasty.

#### 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

Osteoarthritis

#### **Interventions**

- 1. Study and compare the improvement in knee motion and overall function after AP glide and rotating platform design LCS knee arthroplasty.
- 2. Examine the effect of this intervention on proprioception.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

The primary outcome measure for this study will be the improvement in knee motion (as measured by FASTRAK system). This will be done before operation and at three and six months after the operation at bionic laboratory at Hartshill Orthopaedic Surgical Unit.

## Secondary outcome measures

- 1. Proprioception as measured by absolute error angle (this is the difference between actual and perceived angle through which the joint has been moved passively).
- 2. American knee society score, oxford knee score, EuroQol instrument and the Short Form health survey (SF12) will be recorded before and at three months after the operation.
- 3. Complications
- 4. Statistical considerations

#### Overall study start date

20/10/2004

#### Completion date

31/05/2006

# Eligibility

#### Key inclusion criteria

- 1. Patients require a primary bi- or tri- compartmental knee replacement
- 2. Patients require unilateral knee replacement
- 3. Patients have given their voluntary, written informed consent

#### Participant type(s)

Patient

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Target number of participants

50

#### Key exclusion criteria

- 1. Patients are going to have revision knee surgery
- 2. Patients are scheduled to have bilateral knee replacement in one sitting
- 3. Patients suffer from rheumatoid arthritis, diabetes mellitus, post-traumatic arthritis or any form of neurological disorder that can affect the joint position sense
- 4. Patients have had or will require a major knee arthrotomy on the other same side within six months period
- 5. Patients have more than 20 degrees of varus, valgus or flexion deformity

#### Date of first enrolment

20/10/2004

#### Date of final enrolment

31/05/2006

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre

**Keele University** 

Stoke on Trent United Kingdom ST4 7QB

# Sponsor information

#### Organisation

University Hospital of North Staffordshire NHS Trust (UK)

## Sponsor details

Trust Headquarters Royal Infirmary Princes Road Stoke on Trent England United Kingdom ST4 7LN

## Sponsor type

Hospital/treatment centre

#### Website

http://www.nsht.nhs.uk/

# Funder(s)

## Funder type

Government

#### Funder Name

NHS R&D Funding from the University Hospital of North Staffordshire (UK)

# **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?
Protocol article	protocol	31/08/2007		Yes	No