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Anteroposterior glide versus rotating platform low contact stress knee arthroplasty

Submission date	Recruitment status	[_] Prospectively registered
16/11/2006	No longer recruiting	[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

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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