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Is residual soft tissue imbalance following total knee replacement surgery a precursor to biomechanical failure? A prospective study

Submission date
29/09/2006

Registration date
29/09/2006

Last Edited
29/04/2015

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
N0077161778

Study information

Scientific Title
Is residual soft tissue imbalance following total knee replacement surgery a precursor to biomechanical failure? A prospective study

Study objectives
Does identification and reduction of contracted soft tissues surrounding the knee joint result in improved biomechanics of the knee joint, 6 months post operatively? Biomechanics of the knee can be used as an early indicator to prosthetic knee failure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Total knee replacement (TKR)

Interventions
The project subjects will be randomised in the strict order that they are recruited to the study using a standard randomisation table by the main investigator after recruitment to the study.

All of the patients will be treated according to standard operative procedures for total knee replacement surgery and will be fitted with a Genesis 2 surgical prosthesis by the treating consultant. Patients who are allocated to group A will have their soft tissue imbalance assessed by manual palpation of the joint by the surgeon. Group B will be assessed using the balancer /tensor (Stryker Howmedica Osteonics Allendale, HJ) technique of assessment. Soft tissue releases will be carried out on the basis of information available at the time of operation, that is, by observation, palpation and/or movement of the joint. Post operative care will be routine.

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome measure
All of the patients will be assessed clinically using the WOMAC rating scale, during the preoperative assessment and six months post operatively by the second investigator. At the six months stage the biomechanics of the knee joint will be assessed in the Gait and Movement laboratory (Derbyshire Royal Infirmary). The patients will have a number of retro reflective markers positioned on their pelvis, thigh and tibia of the corresponding lower limb and will be asked to walk 10 meters on three separate occasions. The markers will be positioned and data collected by a third investigated. The following outcome measures will be used from the gait evaluations: knee varus/ valgus rotation, knee flexion/extension rotation, knee flexion /extension moment, knee abb/adduction moment.

Secondary outcome measures
Not provided at time of registration

Overall study start date
14/06/2005

Completion date
30/08/2006

Eligibility

Key inclusion criteria
The population for this project will consist of 84 patients who have osteoarthritis of the knee and who have reached the top of the waiting list of one consultant orthopeadic surgeon at Derby Hospitals NHS Foundation Trust. The patients will be recruited to the study approximately two weeks prior to the planned date of surgery, during the standard pre-surgery screening. The recruitment process will be undertaken by the second investigator. The cohort size was determined with a power calculation.

Inclusion Criteria:
1. Patients who are having TKR surgery for osteoarthritis of the knee
2. Patients that are being treated by one consultant orthopaedic surgeon
3. Patients that are having unilateral or bilateral replacements
4. Patients that are having bilateral replacements at different operating centres

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants

84

Key exclusion criteria

1. Patients that are having their knee replaced for rheumatoid arthritis, accident or septic cysts
2. Patients that have undergone previous surgery to the knee such as ligament reconstructions or femoral osteotomy wedges
3. Patients with any neurological, metabolic or vascular disease that might affect proprioceptive feedback mechanisms of the knee
4. Any patient or volunteers that have any other pathological problem that would affect their gait patterns, such as contra lateral amputation, or significant leg length discrepancy

Date of first enrolment

14/06/2005

Date of final enrolment

30/08/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
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Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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