ISRCTN78522557 https://doi.org/10.1186/ISRCTN78522557

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

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 29/04/2015	**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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

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
United Kingdom

England

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

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration