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Trial of gun application vs finger loading of cement for cementation of tibial component in primary total knee replacement

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/11/2014	**Condition category** Surgery	[ ] 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
N0504095061

Study information

Scientific Title

Study objectives
Trial of gun application vs finger loading of cement for cementation of tibial component in primary total knee replacement

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
Patients undergoing total knee replacement surgery will be randomised into two groups.

Group A will have their knee replacement implanted using the current technique of finger packing cement into bone for the femoral component and loading the tibial tray with cement before impaction of the tibial implant.

Group B will have cement applied while still liquid to the tibial plateau using the cement gun before application of the tibial component. Other aspects of bone preparation and cementing will remain unchanged, including use of pulsed lavage and hydrogen peroxide. Initial outcome will be assessed according to radiolucent lines on post-operative radiographs.

Assessments will be performed by a single observer (RKP), blinded to the patients' group allocation.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Long-term outcome will be assessed after 10 years prospective follow-up - revision rate

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2000

Completion date
30/05/2004

Eligibility

Key inclusion criteria
1. Patients undergoing primary total knee replacement for osteoarthritis
2. Males and female inpatients

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
30 subjects and 30 controls

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2000

Date of final enrolment
30/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Orthopaedic Department
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Northumbria Healthcare NHS Trust (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