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Randomised controlled study of the use of electrical muscle stimulation in elective total knee arthroscopy

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/02/2020	**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
N0209157425

Study information

Scientific Title
-

Study objectives
Patients undergoing total knee arthroscopy develop thigh muscle weakness before and after surgery. Recovery from the operation depends on straight leg raise, walking, movement of the knee joint & stair walking, which all require good muscle power/strength.
Electrical muscle stimulation has been shown to be effective in preventing the decrease in muscle strength, muscle mass and oxidative capacity of thigh muscles following knee immobilisation. This study will look a the effect of stimulating the quadracepts and hamstring muscles, to see if it results in improved straight leg raise and flexion of the knee after operation. Effects on pain, muscle size and length of hospital stay will also be examined.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Total knee arthroscopy

Interventions
Patients in the treatment group (50) self-administer daily electrical muscle stimulation for 6-weeks prior to surgery.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Time to actively raise the straight leg after operation
Degree of leg flex 5 days post surgery

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/02/2005

Completion date
31/07/2005

Eligibility

Key inclusion criteria
100 patients who are undergoing an elective total knee arthroscopy

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
1. Revision operations
2. People taking aspirin, clopidogrel or warfarin
3. Patients with bleeding disorders, pace maker, unstable/serious cardiac arrhythmia
4. Patients with dementia, seizure disorders
5. Patients with diabetes or multiple sclerosis, patients with skin disorders, sensitive skin or scars at site of stimulation.

Date of first enrolment
01/02/2005

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal National Orthopaedic Hospital (RNOHT)
Stanmore
United Kingdom
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Sponsor information

Organisation
Department of Health

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Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Royal National Orthopaedic Hospital NHS 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