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Kneehab® pre and post total knee replacement surgery

Submission date	Recruitment status	[X] Prospectively registered
23/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/04/2017	Surgery	[ ] 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
BMR-09-1007

Study information

Scientific Title
The effect of augmenting a standard therapy protocol with a 12-week peri-operative programme of Kneehab® neuromuscular electrical stimulation in patients undergoing total knee replacement: a randomised controlled trial

Acronym
Kneehab

Study objectives
Neuromuscular electrical stimulation (NMES) can help prepare the quadriceps muscle for the rehabilitation phase by building exercise capacity before the operation. The immediate deficit, which normally follows knee surgery, would therefore be compensated to some extent and the post-operative NMES treatment would be expected to counteract the activation inhibition that is thought to occur in the early weeks following surgery. Overall, the patient would be in a better position to benefit from conventional rehabilitation exercises aimed at improved co-ordination and functional performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Royal Liverpool & Broadgreen University Hospital NHS Trust, 30/06/2009

Study design
Randomised controlled blinded parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Patients undergoing total knee replacement surgery

Interventions

Kneehab® group: 6 weeks before and 6 weeks after total knee replacement surgery (30 minutes of NMES twice per day for 12 weeks), plus standard physiotherapy.
Control group: 12 weeks (6 weeks pre and post) standard physiotherapy.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Determine the efficacy of Kneehab® in promoting early recovery of quadriceps performance in patients recovering from total knee arthoplasty as determined by:
1. Clinically significant increase in isometric extensor strength compared to controls
2. Clinically significant reduction in Timed Up-and-Go (TUG) and Stair Climbing Test (SCT) score compared to controls

Secondary outcome measures
1. Quality of life measures
2. Health economic outcomes

Overall study start date
12/04/2010

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Individuals who are scheduled for Total Knee Replacement surgery
2. Individuals who are at least 18 years of age
3. Individuals with a body mass index (BMI) <35
4. Individuals who are walking independently with or without assistive devices
5. Must be able and willing to complete all study assessments and to be followed for the full course of the study
6. Must be able to read, write and follow instructions in English
7. Must be able and willing to provide informed consent
8. Must be willing and able to attend the additional pre-op assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Individuals who have failed the pre-Total Knee Arthroplasty (TKA) operative assessment
2. Individuals with a history of foot and/or ankle pathology
3. Individuals with a history of tibial or femoral fractures
4. Individuals with a history of any underlying neurological conditions
5. Individuals with physical conditions which would make them unable to perform study procedures
6. Individuals with a total hip replacement
7. Individuals undergoing revision TKA of the same operated leg
8. Pregnant women or inadequate precautions to prevent pregnancy
9. Diagnosis of a medical condition that would contraindicate treatment with the product, e.g. skin lesions at electrode site
10. Individuals with an active implanted medical device (i.e. pacemaker, pump)
11. Individuals with a history of stroke
12. Individuals with a history of neurological disorder that affects lower extremity function (stroke, peripheral neuropathy, Parkinsons disease, multiple sclerosis, etc.)
13. Individuals with a diagnosis of inflammatory arthritis (rheumatoid arthritis, gout or psoriatic arthritis)
14. Individuals with muscle diseases (i.e. muscular dystrophy)
15. Visible skin injury or disease on their legs
16. Principal investigator for this study, or member of study staff

Date of first enrolment
12/04/2010

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Liverpool & Broadgreen University Hospital
Liverpool
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L14 3LB

Sponsor information

Organisation
The Royal Liverpool & Broadgreen University Hospital (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/009sa0g06

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Liverpool & Broadgreen University Hospital (UK)

Funder Name
Bio-Medical Research, Ltd., (Ireland) - provide Kneehab (NMES) devices

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