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Role of exercise and diet in disuse atrophy in hip surgery patients

Submission date	Recruitment status	[X] Prospectively registered
15/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Musculoskeletal Diseases	[ ] 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

N/A

Study information

Scientific Title
The role of pre-surgery training and protein supplementation in the mitigation of disuse muscle atrophy in patients undergoing elective hip arthroplasty.

Study objectives
The normal loss of skeletal muscle mass and strength associated with old age (sarcopenia) poses a particular risk to the elderly when affected by illness or injury resulting in a period of immobilisation. Such situations, including immobilisation due to hip-fracture surgery, are common amongst the elderly population. The resulting disuse atrophy, particularly of the skeletal muscle of the lower limb, is a large contributing factor to the poor rehabilitation and high morbidity and mortality associated with incidences such as hip fracture. It has been shown that essential amino acid supplementation can stimulate muscle protein synthesis in both elderly individuals and young volunteers subject to conditions of chronic unloading. Furthermore, as skeletal muscle retains its capacity for adaptation into old age there is increasing evidence that older as well as younger individuals can limit and even reverse to a certain degree atrophy-associated muscle weakness by inducing neuromuscular and tendinous adaptations with resistance strength training programs.
At present, the limited previous research into the effects of chronic unloading in the elderly make it difficult to determine the extent with which reduction in muscle mass or decreased levels of physical activity are responsible for the characteristic loss of muscle strength associated with old age. Further research is necessary to examine the relationship between muscle function and chronic disuse to address this problem. It has been shown that knee and hip arthroplasty patients with better preoperative quality of life and physical function have less pain and better postoperative physical function than those with a lower level of preoperative physical activity. Combining preoperative strength training and essential amino acid (leucine) supplementation may increase muscle strength and function and as a result may mitigate the loss of muscle mass, hence increasing preoperative physiological reserve, potentially improving speed and extent of recovery of elderly patients following surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Research Ethics Committee submission pending

Study design
Single-centre double-blind placebo controlled longitudinal study

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Sarcopenia

Interventions
Interventions will consist of resistance training programs combined with essential amino acid (leucine) supplementation or non-essential amino acid (alanine) supplementation for 10 weeks, pre-surgery.

Participants in the training groups will be supplied with Thera-band® resistance exercise bands and instructed on how to perform resistance exercises aimed to build up and strengthen the knee extensor (quadriceps femoris) muscles. Participants will be asked to train three times weekly at home and will keep regular exercise diaries so exercise regimes can be monitored. Participants will also be contacted throughout the training period to ensure exercises are completed properly and to provide an opportunity for participants to ask any questions or resolve any issues they may have during the training. Participants will train for 10 weeks while awaiting surgery.

Participants will be asked to take daily oral suspensions containing either an essential amino acid, commercially available leucine (0.6g/kg body weight) (isolated from cows milk) or placebo, a non-essential amino acid alanine (same dosage). All participants will be asked to stop taking any nutritional supplementation at least one month before the study begins. Participants will be asked to take essential amino acid and placebo supplements once daily but not within 1 hour before or after resistance training during the training period.

The total duration of follow-up will be 3 months post surgery.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Muscle thickness and architecture, measured by ultrasound
2. Muscle strength, measured by dynamometer
These outcomes will be assessed at baseline (10 weeks prior to surgery), immediately prior to surgery, and at 1 and 3 months post surgery.

Secondary outcome measures
None

Overall study start date
01/01/2011

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Elderly patients (60+ years), males and females, awaiting elective total hip arthroplasty but otherwise in relatively good health
2. Participants must have a good understanding of English to understand verbal explanations and written information given in English
3. Participants must be able to give fully informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
45

Key exclusion criteria
All participants will be screened by a physician and will be excluded from the study if they suffer from or have ever suffered from:
1. Previous stroke
2. Uncontrolled cardiovascular disease
3. Motor neurone disease
4. Parkinson's disease
5. Medically diagnosed osteoporosis
6. Type II diabetes
7. Hypertension or myocardial infarction within the previous 2 years
8. Acute febrile or systemic disease within the past 2 years
9. Currently taking beta blockers

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute for Biomedical Research into Human Movement and Health
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Sponsor information

Organisation
Barts and the London School of Medicine (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Research council

Funder Name
EU Seventh Framework Programme (FP7) (Europe)

Funder Name
Institut National de la Sante et de la Recherge Medicale (INSERM) (France)

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