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The ELMS Trial: ELectrical and Magnetic Stimulation to mitigate Intensive Care Unit-acquired weakness after trauma

Submission date
18/09/2013

Recruitment status
No longer recruiting

Registration date
19/09/2013

Overall study status
Completed

Last Edited
13/03/2020

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Immobilisation causes the size and strength of the muscles to reduce quickly. Intensive Care Unit-Acquired Weakness is a common problem which is not well understood. A combination of wasting of muscle and inflammation affecting nerves and muscles can cause loss of function and reduced quality of life. This can have long-term consequences, lasting for years. Previous studies suggest that artificially stimulating muscle activity in intensive care patients may reduce these processes. This has never been tested amongst a group of patients who have all had major injuries. Previous research has mainly looked at stimulation of leg muscles with electricity. The use of magnetic stimulation has never been tested. We will find out if stimulation of the arms in patients who have been admitted to the ICU due to major injury will stimulate the arms (due to their importance in activities of daily living) and will find out about the role of magnetic stimulation as an alternative to electrical stimulation. This is an initial (small-scale) study. This means that the main aim of this study is to collect enough information to tell us how many patients would have to be studied to provide a definite answer about the possible benefits of stimulation.

Who can participate?
Patients who have severe injuries who are admitted to the critical care unit at the Queen Elizabeth Hospital, Birmingham, can participate in this study.

What does the study involve?
Participants will receive either active electrical, active magnetic or sham stimulation. This will be chosen at random, with an equal chance of receiving any given stimulation. The stimulation will be applied to their arms every day for ten days. Blood samples will be taken when the participant agrees to take part and before and after the stimulation on three occasions. Before the stimulations begin, muscles in the arms will be assessed with ultrasound and a small sample (called a biopsy) will be taken from the biceps muscle. These will be done again at the end of the ten-day stimulation period. At the end, electrodes will be attached to the hands and arms in order to test the function of various nerves. These tests are known as nerve conduction studies. Tests of arm muscle strength will also be performed. When the participant is ready to leave the

hospital, their ability to perform activities of daily living (feeding, dressing, walking, etc) will be assessed. Their quality of life will be measured at the time of discharge and six months later.

What are the possible benefits and risks of participating?
It is possible that participants who receive active stimulation might retain more strength in their muscles and be able to do more than patients who receive sham stimulation. Muscle biopsy carries slight risks (such as bleeding, discomfort or infection) and nerve conduction studies may be uncomfortable.

Where is the study run from?
The study is run from Queen Elizabeth Hospital, Birmingham, UK.

When is study starting and how long is it expected to run for?
The study is expected to start in late 2013. It is expected that patients will be recruited over a six-month period with follow-up continuing for a further six months after recruitment is completed.

Who is funding the study?
The study is funded by the NIHR Surgical Reconstruction & Microbiology Research Centre, UK.

Who is the main contact?
Mr Iain Smith
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15027

Study information

Scientific Title
A pilot randomised controlled trial of electrical and magnetic stimulation against sham to mitigate intensive-care-unit-acquired weakness after trauma

Acronym
ELMS

Study objectives
The study is a Phase II pilot, testing the hypothesis that upper limb muscle stimulation can reduce the incidence of intensive care unit acquired weakness after major trauma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethic Committee (MREC); Approval date 28/08/2013; Ref: 13/YH/0246

Study design
Randomised; Interventional; Design type: Prevention, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
ICU-acquired weakness

Interventions
1. Electrical stimulation: bilateral transcutaneous electrical stimulation of upper limb muscles for one hour daily for 10 days
2. Magnetic stimulation, 45 minutes of stimulation to each upper limb for 10 days
3. Sham electrical stimulation: simulated bilateral upper limb electrical stimulation for one hour daily for 10 days

4. Sham magnetic stimulation: 45 minutes of apparent stimulation per day for 10 days, with an intensity below that required to cause muscle contraction

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Incidence of ICU-Acquired Weakness
Timepoint(s): Day after completion of intervention regimen or at first point where participant can be assessed

Secondary outcome measures
1. Critical Care Unit and Hospital length of stay; Timepoint(s): At discharge from CCU and hospital
2. Grip strength and MRC Sumscale of upper limb muscles; Timepoint(s): Day after completion of intervention or earliest point at which participant can be assessed
3. Inflammatory profile during intervention; Timepoint(s): Day 0, 3, 6 and 10
4. Interval to independent mobilisation; Timepoint(s): during hospital stay
5. Interval to independent transfer from bed to chair; Timepoint(s): During hospital stay
6. Muscle architecture; Timepoint(s): Biceps biopsy taken on day after completion of stimulation
7. Nerve conduction studies; Timepoint(s): Day after completion of stimulation regimen
8. Northwick Park Dependency Score; Timepoint(s): Hospital discharge
9. Quality of Life; Timepoint(s): Hospital discharge and 6 months post- discharge

Overall study start date
01/10/2013

Completion date
01/04/2014

Eligibility

Key inclusion criteria
Patients must:
1. be aged 16 years old or over
2. have been able to transfer independently from bed to chair prior to injury
3. be admitted to the Critical Care Unit at Queen Elizabeth Hospital, Birmingham as result of traumatic injury
4. have an anticipated length of stay of at least 2 weeks
5. give consent (or, if lacking capacity at screening, have a personal or professional consultee indicate that they would be likely to give consent were they not lacking capacity)
Target Gender: Male & Female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
Patients must not:
1. refuse to allow their GP to be informed of participation
2. have known systemic neuromuscular disease (e.g. Guillain Barré Syndrome) at ICU admission
3. have known pathology affecting the brain, causing weakness (e.g. stroke or bleeding in the brain) at the time of Critical Care Unit admission
4. have any pacemaker (e.g., cardiac, diaphragm, gastric) or implanted cardiac defibrillator, neurostimulator, intracardiac line or cochlear implant
5. have any metallic implants or foreign bodies in the areas to be stimulated
6. have any metal (other than titanium) in the head or brain
7. have known or suspected malignancy in any limb
8. be pregnant
9. have a body mass index =35 kg/m2
10. have been an critical care patient for more than 7 days prior to enrolment
11. be moribund (i.e. >90% probability of patient mortality in the next 96 hours)
12. have any limitation in life support at the time of enrolment other than an instruction not to attempt cardiopulmonary resuscitation in the event of cardiac arrest
13. have upper limb fractures

Date of first enrolment
01/10/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Clinical Research Fellow Acute Surgery
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Surgical Reconstruction & Microbiology Research Centre, 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No