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E-Vent: Electrical muscle stimulation in mechanical Ventilation

Submission date	Recruitment status	[ ] Prospectively registered
31/01/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/01/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2019	Respiratory	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Muscle wasting is common in intensive care patients and many patients are discharged with profound weakness which may continue long after they have left hospital. Wasting starts early and may be rapid. There are limited physiotherapy techniques which prevent it in the early stages of illness. Electrical muscle stimulation (EMS) is a method of exercising muscles by passing electrical current through skin electrodes. It has been tested extensively on other patient groups and can prevent muscle wasting and improve strength. Some research has used EMS on ICU patients, but these studies are too small to make definite decisions about how it works and whether it should be used routinely. This study will test EMS in ICU patients, and measure whether it prevents muscle wasting, and improves strength and function.

Who can participate?
Critically ill patients aged 18 or over, expected to receive prolonged mechanical ventilation (breathing supported by a machine).

What does the study involve?
Patients entering the ICU will be screened at time of admission for eligibility, and their relatives will be asked about their likely wish to participate in this study. Participants will be randomly allocated to one of two groups: one group will receive daily EMS and the other group will receive sham EMS, which is set up the same way but does not cause muscle contraction. Both groups will also receive the usual rehabilitation. Measurements of muscle thickness will be performed using ultrasound during the ICU stay and strength and function will be tested at ICU and hospital discharge. Blood samples will be taken to help understand how EMS affects the muscles, and patients will be sent a questionnaire at 90 days after their ICU admission.

What are the possible benefits and risks of participating?
This study will help inform physiotherapists and ICU staff whether EMS should be used routinely in the UK and internationally.

Where is the study run from?
Bristol Royal Infirmary (UK).

When is the study starting and how long is it expected to run for?
October 2012 to September 2013.

Who is funding the study?
Intensive Care Foundation UK.

Who is the main contact?
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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
12700

Study information

Scientific Title
The effects of electrical muscle stimulation on muscle mass, strength and function in patients receiving mechanical ventilation: a randomised controlled, single-blind feasibility study

Acronym
E-Vent

Study objectives

Muscle wasting is common in critically ill patients and many develop profound weakness which may continue long after they have left hospital. Wasting starts early after admission and may be rapid. Limited physiotherapy techniques can prevent it in the early stages of illness.

Electrical muscle stimulation (EMS) is a method of exercising muscles by passing electrical current through skin electrodes. It has been tested extensively on other patient groups and can prevent muscle wasting and improve strength. Some research has used EMS on intensive care unit (ICU) patients, but these studies are too small to make definite decisions about how it works and whether it should be used routinely. This study will test EMS in ICU patients, and measure whether it prevents muscle wasting, and improves strength and function.

Patients admitted to the Bristol Royal Infirmary ICU will be recruited to this study, where the research team is experienced in conducting studies involving critically ill patients. Because ICU patients are often unconscious and unable to make decisions, their relatives will be asked about their likely wish to join this study. The research team will apply EMS to the arm and thigh muscles twice daily. One group of patients will receive EMS and usual rehabilitation, and a second group will receive usual rehabilitation and sham (dummy) EMS, which is set up in the same way but does not cause muscle contraction. Measurements of muscle thickness using ultrasound will be performed during the

ICU stay and strength and function will be tested at ICU and hospital discharge. Blood tests will be taken to help understand how EMS affects the muscles. Participants will be sent a questionnaire 90 days after their ICU admission.

This will help inform physiotherapists and ICU staff whether EMS should be used routinely in the UK and internationally.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12700

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Frenchay, 25/06/2012, ref: 12/SW/1077

Study design
Parallel-group randomised sham-controlled feasibility clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Critically ill patients receiving prolonged periods of mechanical ventilation

Interventions
Electrical muscle stimulation twice daily 30 minute sessions of electrical muscle stimulation to biceps and quadriceps, for duration of critical care stay.

Intervention Type
Device

Primary outcome measure
Ultrasound quadriceps muscle layer thickness; Timepoint(s): Baseline, study days 4,7 and every 3 days, ICU discharge, hospital discharge

Secondary outcome measures
1. US (composite score: mid thigh, forearm and upper arm; rectus femoris cross sectional area)
2. Manual muscle Testing individual and composite muscle strength scores
3. Handgrip strength
4. Hand held dynamometry limb muscle strength
5. Barthel Index (BI) physical function score
6. Six-minute walk test
7. SF-36 (v2) health related quality of life questionnaire
8. Surrogate muscle biomarkers (serum c-reactive protein (CRP), plasma creatine kinase (PCK), plasma 3 methyl histidine (P3-MH), urinary creatine kinase (UCK) and 3 methyl histidine (U3- MH)
9. MV days
10. ICU, hospital and 90 day mortality
11. ICU and hospital length of stay (LOS)
12. Hospital resource use at discharge

Overall study start date
01/10/2012

Completion date
30/09/2013

Eligibility

Key inclusion criteria
1. The target population is critically ill patients expected to receive prolonged mechanical ventilation (MV)
2. 18 years or older, male and female
3. Expected to receive MV for > 72 hour

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 28; UK Sample Size: 28

Key exclusion criteria
1. Body mass index < 15 kg/m² or > 35kg/m²
2. Pre-existing neuromuscular conditions affecting peripheral nervous system
3. Pacemaker or implanted cardiac defibrillator
4. Skin lesions making electrode placement impossible
5. Current upper and/ or lower limb fractures
6. Current pregnancy
7. Unable to walk or perform transfers prior to acute illness
8. Chronic renal disease
9. Chronic liver failure (Child Pugh score >3)
10. Irreversible disease with < 6 months prognosis
11. Long term oral steroid use >10mg
12. Uncontrolled / difficult to control epilepsy

Date of first enrolment
01/10/2012

Date of final enrolment
30/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Trust (UK)

Sponsor details
Research & Innovation Department
Education Centre
Upper Maudlin Street
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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Intensive Care Foundation UK (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration.

Results posted on University Hospitals Bristol NHS Foundation Trust website: http://www.uhbristol.nhs.uk/research-innovation/our-research/grants-and-infrastructure-awards/above-and-beyond-research-capability-funding/completed-grants/effects-of-electrical-muscle-stimulation-physical-functional-outcomes-in-patients-receiving-prolonged-mechanical-ventilation/

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration