

# E-Vent: Electrical muscle stimulation in mechanical Ventilation

<b>Submission date</b> 31/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/01/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/04/2019	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Judith Edwards  
Judith.Edwards@UHBristol.nhs.uk

## 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/m<sup>2</sup> or > 35kg/m<sup>2</sup>
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  
Bristol  
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United Kingdom  
BS2 8HW

**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