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A feasibility study of early and enhanced rehabilitation in ICU

Submission date
13/08/2015

Recruitment status
No longer recruiting

Registration date
13/08/2015

Overall study status
Completed

Last Edited
19/11/2020

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many patients after an illness in the Intensive Care Unit (ICU) are left feeling very weak and struggle to get their strength back. Patients lose muscle mass whilst they are on a breathing machine, which causes muscle weakness. Survivors of critical illness can still be weak many months or even years after hospital discharge which significantly affects quality of life. It is recognized by the National Institute of Health and Care Excellence (NICE) that we need to provide physiotherapy and rehabilitation for patients within the ICU and in the recovery period, but how and when to deliver this is still uncertain. At present, most patients in the UK receive only limited physiotherapy whilst on the ICU. In the United States, it has been demonstrated that providing earlier and more structured physiotherapy on the ICU is safe and can improve a patient's wellbeing and reduce length of stays within the ICU and hospital. However, it is uncertain whether these findings are relevant to the NHS. This study compares two different strategies (types) of rehabilitation and investigates the impact of these strategies on the patient' s immune and endocrine (hormone) function. The results will help in the development of another, larger, study.

Who can participate?
Patients of at least 16 years of age who are critically ill and that have been mechanically ventilated for at least 5 days.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (standard rehabilitation group) are given the physiotherapy routinely provided to all patients in critical care at Queen Elizabeth Hospital Birmingham. Those in group 2 (early rehabilitation group) are given structured physiotherapy earlier within the course of a patient's illness and continuing this programme for as long as the patient is in ICU and carrying on upon their discharge onto the ward. The two approaches are assessed to find out whether one is better than the other by using measures of patient wellbeing, mobility and recovery, and looking at length of stays on the ICU and in hospital. Weekly blood and urine samples are also taken for tests to assess immune and endocrine function.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
June 2016 to May 2017

When is the study starting and how long is it expected to run for?
University Hospital Birmingham NHS Foundation Trust (UK)

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Ms Lauren Cooper

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
19092

Study information

Scientific Title
A feasibility study of early and enhanced rehabilitation in critical care and potential impact on immunoendocrine function

Study objectives
Critical illness causes significant muscle wasting and weakness, and survivors of critical illness suffer from significant physical morbidity for months and sometimes years after hospital discharge. Starting rehabilitation with physiotherapy on the intensive care unit (ICU) has been shown to be effective in the US, but it is unknown whether this is generalisable to the NHS. This

is a single site feasibility randomised controlled trial comparing two different strategies of rehabilitation and investigating the impact on immune and endocrine function. The results will inform the design of a larger multicentre study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham 1, 08/04/2015, ref: 15/EM/0114

Ethics approval for extension of study was approved on 20/05/2016. ref: RRK5305, amendment ref: SA 1.31 3/4 18.03.16

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Critical care; Subtopic: Critical care; Disease: All Critical care

Interventions
Patients are randomized to standard care or enhanced rehabilitation.
1. Standard care (control group):
Regardless of the day of admission, all patients are assessed by the physiotherapy team within 24 hours of admission to critical care to obtain background information on reason for admission, as well as any pre existing conditions that may be relevant. They then continue to be seen on a daily basis on weekdays, with rehabilitation commencing based on the individual physiotherapists own clinical reasoning. Physiotherapy provision is funded at a ratio of 1 physiotherapist to 10 patients, with an average treatment time of 30 - 45 minutes per patient per day Monday to Friday with one physiotherapist. Rehabilitation provision is individually prioritised with no set structure or format for rehabilitation in place, and only limited rehabilitation currently takes place whilst the patient is mechanically ventilated. When discharged to the ward environment, a telephone handover is provided to the receiving therapist who then continues the rehabilitation until the patient is deemed safe for discharge, with no further input provided by the critical care team.
2. Early and structured rehabilitation (intervention group):
The process of structured critical care rehabilitation which will be adopted for the management of the treatment group, is shown in Figure 1 and Figure 2 below. To summarise, during the acute phase of a patients illness whilst they are still sedated and/or paralysed rehabilitation is confined to the bed with daily passive movements and positioning. As soon as patients are stable and awake enough to commence more active mobilisation they are assessed by sitting on the edge of the bed, allowing an assessment to be made of sitting balance, exercise capacity and physiological stability. This is performed with endotracheal tubes or tracheostomies still in situ, and whilst the patient is still on ventilatory and/or renal support and low levels of vasopressor or inotropic support. Following this assessment and as strength increases, a rehabilitation plan is formulated which includes the patient sitting out of bed in a chair using the most appropriate

method for transfers. More active rehabilitation is administered as the patient improves to progress to standing, transfers and walking. A key worker will conduct a comprehensive assessment of the patient, which will be completed within 24 hours of randomisation. This will provide background information regarding physical function, any psychological history and pre admission exercise capacity to allow an individually tailored rehabilitation programme to be devised. To facilitate ongoing rehabilitation following critical care discharge both verbal and written handovers will be provided to ward therapy staff. Ongoing rehabilitation will continue to be provided by the critical care team in conjunction with the ward therapists for the first week following discharge from critical care to ensure a seamless handover of care and maximise ongoing rehabilitation.
3. Both groups:
All other medical care will be at the discretion of the responsible intensivist. Rehabilitation interventions by all members of the clinical team at each stage of the patient pathway will be carefully recorded, with analysis of the reasons for missed rehabilitation sessions performed. In accordance with current unit practice, all patients with a length of stay over 14 days will be discussed at weekly multidisciplinary team meetings which include consultant medical staff, senior nursing staff, speech and language therapists and occupational therapists, with collaborative treatment goals set, reviewed and updated.

Intervention Type
Other

Primary outcome(s)
Critical care and hospital length of stay

Key secondary outcome(s))
1. Efficacy:
1.1. Manchester Mobility Score at baseline and critical care discharge – This will highlight any differences seen in baseline mobility at the point of recruitment and track any functional changes achieved within critical care by the intervention strategies
1.2. Ventilator days – To assess whether the intervention and any associated physical improvements lead to an earlier liberation from ventilatory support.
1.3. ICU, Hospital and 2 year mortality – It has been suggested that improving physical status and reducing ICU length of stay may serve to reduce mortality both within critical care and the hospital.
1.4. Total hospital length of stay – To assess whether enhanced rehabilitation services within critical care and continuing onto the wards can also reduce the post-ICU length of stay.
2. Patient focused outcomes:
2.1. Functional status: Barthel index score at baseline (estimated), critical care discharge, hospital discharge, 3 and 12 months – To assess the impact of the rehabilitation programmes on function during activities of daily living at hospital discharge and through the post-discharge period.
2.2. Health related quality of life: SF36 at baseline (estimated), critical care discharge, hospital discharge, 3 and 12 months - to assess whether enhanced rehabilitation programmes improve patient-reported measures of health status.
2.3. Anxiety and depression: HADS score – at critical care and hospital discharge – to assess whether structured programmes of rehabilitation improve the psychological impact of critical illness and recovery.
3. Mechanism:
3.1. Muscle thickness of quadriceps, thenar eminence, biceps and rectus abdominus – to assess whether enhanced physiotherapy attenuates the reduction in muscle thickness seen in critical

illness
3.2. Serum Cortisol:DHEAS ratios – to assess ratios in prolonged critical illness and examine any changes induced by enhanced physiotherapy
3.3. Urinary corticosteroid metabolite profiles and relationship to vitamin D status in prolonged critical illness
3.4. Neutrophil function – to assess neutrophil function in prolonged critical illness and any changes induced by enhanced physiotherapy
3.5. Cytokine flux – to assess whether rehabilitation influences the balance between pro and anti-inflammatory cytokines in chronic critical illness

Completion date
31/05/2017

Eligibility

Key inclusion criteria
1. Age ≥16 years
2. Patients who have received mechanical ventilation for ≥ 5 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
103

Key exclusion criteria
1. Profound neurological deficit
2. Orthopaedic patients with contraindications to mobilise (e.g. pelvic / spinal fractures)
3. Poor prior level of mobility (<10yds)
4. Neuromuscular disease (e.g. Motor Neuron Disease)
5. Mechanical ventilation > 48 hours at another facility prior to admission
6. Expected withdrawal of treatment within the next 24 hours
7. Patients with already established rehabilitation pathways (e.g. amputees)
8. Previous participation in this study

Date of first enrolment
01/06/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital Birmingham NHS Foundation Trust
NIHR SRMRC, Research and Development
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Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	19/11/2020	Yes	No
Protocol article	protocol	17/04/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes