ISRCTN24998809 https://doi.org/10.1186/ISRCTN24998809

Musculoskeletal problems following critical illness

Submission date
31/12/2021

Recruitment status
No longer recruiting

Registration date
21/03/2022

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The intensive care unit (ICU) is a vital part of hospital care, with more patients requiring treatment in the ICU each year. However, patients who survive ICU often experience long-term physical problems resulting in a poor quality of life. There have been several studies investigating rehabilitation after ICU. These have demonstrated little benefit on physical function, exercise capacity or quality of life. Musculoskeletal (MSK) problems are those that affect bone, muscle and joints. MSK problems affect 25% of the UK population and limit people' s ability to work. To date, there has been a small amount of research that has shown that ICU survivors are likely to experience MSK problems that would potentially benefit from physiotherapy. The aim of this study is to evaluate the overall MSK health of patients, 6 months after they were admitted to ICU.

Who can participate?
Adult patients who have spent more than 2 days in the ICU

What does the study involve?
The participants will be phoned 6 months after they were admitted to the ICU and will be asked several questionnaires. These questionnaires will gather information on their MSK health, employment and quality of life. Participants who report a MSK problem during the telephone conversation will be invited to have one of two assessments visits. One group of patients will undergo a full MSK assessment with a physiotherapist. This will include pain, muscle and joint assessment. A smaller group of patients with severe MSK problems will undergo the same MSK assessment as above plus some additional tests which will be performed at Oxford Brookes University. They will be asked about their function, have an ultrasound scan, undertake a walking test and be given a wristband to record how active they are for a week after their visit.

What are the possible benefits and risks of participating?
As this research is focused on using information, some of which is already routinely collected, so the risk of harm is very low. Questionnaires assessing the symptoms of participants used at the telephone follow-up do assess symptoms that may cause mild distress to participants. If this occurs, participants will be offered advice on avenues for support such as ICU support groups, and any clinically concerning information that is reported by participants at any point will be

discussed with their GP.
Participants may experience discomfort or pain as part of the assessment process, which is common during any musculoskeletal assessment and will be minimised by the research team.
The researchers do not promise the study will help participants in particular, but the information they get from this study may help improve the NHS treatment for people recovering from critical illness in the future.

Where is the study run from?
Oxford University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2018 to June 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Owen Gustafson
owen.gustafson@ouh.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mr Owen Gustafson

ORCID ID
http://orcid.org/0000-0002-5450-3696

Contact details
Therapies Clinical Service Unit
Physiotherapy Department
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 221543
owen.gustafson@ouh.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
296030

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS 50989, IRAS 296030

Study information

Scientific Title
Evaluating the musculoskeletal health state of intensive care unit survivors: a multicentre observational study

Acronym
MSK-ICU

Study objectives
To determine and characterise the musculoskeletal (MSK) health state of intensive care unit survivors 6 months following admission to intensive care, in order to inform future development of targeted rehabilitation interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2021, North of Scotland Ethics Committee 2 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; gram.nosres@nhs.scot), REC ref: 21/NS/0143

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal health state of intensive care unit survivors

Interventions

In this observational study, the researchers will recruit 322 adult patients who have spent more than 2 days in the ICU and follow these patients up by telephone questionnaire 6 months following their admission to ICU. The researchers believe that following an admission to ICU, patients may be experiencing musculoskeletal problems that are contributing to poor physical function. They will evaluate patients musculoskeletal health state and identify and factors associated with poor musculoskeletal health after critical illness.

Intervention Type
Other

Primary outcome measure
Musculoskeletal health state measured using the Musculoskeletal Health Questionnaire (MSK-HQ) at 6 months

Secondary outcome measures
Measured at 6 months:
1. Health-related quality of life measured using the EuroQol 5D (EQ-5D)
2. Anxiety and depression measured using the Hospital Anxiety and Depression Scale (HADS)
3. Subjective distress measured using the Impact of Events Scale-Revised (IES-R)
4. Employment measured using an employment questionnaire

Overall study start date
01/06/2018

Completion date
26/06/2023

Eligibility

Key inclusion criteria
Patients who have been admitted to ICU for 48 hours or more

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 332; UK Sample Size: 332

Total final enrolment
334

Key exclusion criteria

1. Patients who are judged to lack capacity at the time of consent as defined by the Mental Capacity Act (2005)
2. Proven or suspected acute primary brain pathology, spinal cord injury or other neuromuscular disease resulting in proven or prolonged weakness
3. Admitted to the intensive care unit with musculoskeletal complications or trauma
4. Patients who were dependent for activities of daily living in the month prior to current intensive care unit admission (gait aids are acceptable)
5. Patients who have a palliative diagnosis/treatment pathway
6. Prisoners
7. Patients with no fixed abode
8. Patients who are unable to communicate clearly in English over the telephone for 20 minutes
9. Patients refusing consent

Date of first enrolment
23/02/2022

Date of final enrolment
02/01/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Milton Keynes University Hospital
Standing Way
Eaglestone

Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

Sponsor details
Research and Development Department
Joint Research Office
Second Floor
OUH Cowley
Unipart House Business Centre
Garsington Road
Oxford
England
United Kingdom
OX4 2PG
+44 (0)1865 223714
ouh.sponsorship@ouh.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type

Government

Funder Name
NIHR Academy; Grant Codes: NIHR301569

Results and Publications

Publication and dissemination plan
The findings of this research study will be published in research journals, presented at national and international conferences. Locally the findings will be presented to patients, staff and researchers. Planned publication in a peer-reviewed journal in July 2024. A full study protocol will be published and a link will be made available.

Intention to publish date
31/07/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 4	04/12/2022	12/12/2022	No	No
Protocol article		02/02/2023	03/02/2023	Yes	No
Statistical Analysis Plan	version 1.0	07/06/2023	09/06/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		27/03/2024	25/07/2024	Yes	No