

Musculoskeletal problems following critical illness

Submission date 31/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 21/03/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/07/2024	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

296030

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

ROR

<https://ror.org/03h2bh287>

Funder(s)

Funder type

Government

Funder Name

NIHR Academy; Grant Codes: NIHR301569

Results and Publications

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?
Results article		27/03/2024	25/07/2024	Yes	No
Protocol article		02/02/2023	03/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4	04/12/2022	12/12/2022	No	No
Statistical Analysis Plan	version 1.0	07/06/2023	09/06/2023	No	No