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Muscle mass loss and nutrition in critically ill children

Submission date	Recruitment status	[X] Prospectively registered
24/08/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/09/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/07/2024	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Although children's intensive care in the UK has improved in the last decade, for some children who stay a longer time, their recovery can be prolonged both physically and psychologically. Children on the breathing machine in intensive care can lose a lot of weight and muscle, and this slows down their recovery and can lead to longer stays both in the intensive care and in hospital. In adults in intensive care, research has shown that some of this muscle loss may be able to be lessened by giving them a higher protein feed combined with early rehabilitation in intensive care, but in children we still do not know if this weight and muscle loss is modifiable by and related to the nutrition and the amount of protein they receive. This is the aim of this study, as children are not the same as adults and frequently respond in different ways to adults. It is important to understand what happens to the child's muscles after the child leaves intensive care and the hospital.

Who can participate?
Children (aged 0-16 years) who are admitted to the pediatric intensive care unit (PICU) and are on a breathing machine, who are expected to stay on this for more than 48 hours and who are being fed through a tube into their stomach.

What does the study involve?
If the parent/carer decides to allow their child to participate in this study, one of the researchers (who are children's intensive care trained specialist nurses, physiotherapists, or a doctor) will get written consent form for the study. Then they will use a special ultrasound machine to look at the child's thigh muscle (using gel and running a probe over the muscle, which does not hurt at all). They will do this measurement within 24 hours after the child is admitted to intensive care, and then on days 3, 5, 7 and 10 if the child stays that long. They will do this both when the child is asleep (sedated) and as they wake up, when they leave intensive care, when they are about to leave the hospital and 3 months later. The other information collected is about how much food (protein and calories) the child is getting and blood values can be calculated as usual from the child's daily medical records. This will allow the researchers to see what happens to their muscles and how strong their muscles are, in addition to how much nutrition and protein they got in intensive care to see if they are related. The researchers will also look at one of their usual daily blood tests in intensive care (no extra blood will be taken) and collect information about

their age and weight, why they came to intensive care and other important things that might impact on their muscles. They will also ask the child and parents some questions about their child's activities at various time points and after 3 months (these will be the same questions each time). After 3 months (at the 3-month visit) the researchers will ask the child and or family to complete a simple (one average week) diet and activity diary for their child.

What are the possible benefits and risks of participating?
There are no additional risks to the child from being in this study. The muscle ultrasound is pain-free and completely non-invasive. The only burden to parents is the extra time required for the 3-month follow up visit, but the researchers will time this with the child's closest follow-up hospital appointment and cover their travel and parking expenses. It is also possible to allow the child to be a part of this study and only have a brief telephone interview at 3 months (if it is not possible to come back for an extra visit). There are no benefits from being in the study.

Where is the study run from?
Alder Hey Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2020 to September 2023

Who is funding the study?
The NIHR Research for Patient Benefit (RfPB) funding stream (UK)

Who is the main contact?
Associate Prof. Lyvonne Tume
Lyvonne.Tume@edgehill.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
301263

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.1, IRAS 301263, CPMS 49787

Study information

Scientific Title
A prospective observational study to explore the relationships between nuTRition, protein intake ANd muScle mass loss during and after Pediatric Intensive caRE

Acronym
TRANSPIRE

Study objectives
To examine the relationships between muscle mass loss (measured via non-invasive ultrasound of the muscles) with nutritional intake and inflammatory markers during and after critical illness using standard, readily available bedside equipment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/07/2021, Liverpool Central Ethics Committee (address: not available; +44 (0)207 104 8197; liverpoolcentral.rec@hra.nhs.uk), REC ref: 21/NW/0192

Study design
Prospective observational single-centre study

Primary study design
Observational

Secondary study design
Prospective observational single-centre study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Muscle mass loss during and after pediatric intensive care

Interventions
The researchers will use a special ultrasound machine to look at a child's thigh muscle (using gel and running a probe over the muscle, which does not hurt at all). The researchers will do this measurement within 24 hours after the child is admitted to intensive care, and then on days 3, 5, 7 and 10 if the child stays that long. They will do this both when the child is asleep (sedated) and as they wake up, when they leave intensive care, when they are about to leave the hospital and 3 months later. The other information collected about how much food (protein and calories) the child is getting and blood values can be calculated as usual from their daily medical records. This will allow the researchers to see what happens to their muscles and how strong their muscles are, in addition to how much nutrition and protein they got in intensive care to see if they are related. The researchers will also look at one of their usual daily blood tests in intensive care (no extra blood will be taken) and collect information about their age and weight, why they came to intensive care and other important things that might impact on their muscles. They will also ask the parent some questions about their child's activities at various time points and after 3 months (these will be the same questions each time).
If the child is coming back to the hospital for any follow up, the researchers will time this 3-month measurement with their hospital visit or the parents can choose to come back at a separate time for this 3-month visit. For this 3-month visit the researchers will ask the parents and/or child to complete a simple (one average week) diet and activity diary for their child.

Intervention Type
Other

Primary outcome measure
1. PICU muscle wasting assessed using ultrasound at days 1, 3, 5, 7 and 10 of PICU stay, hospital discharge and 3 months
2. Protein intake during critical illness assessed using nitrogen balance (g/day) from admission to PICU discharge

Secondary outcome measures
1. Energy intake during critical illness assessed using electronic hospital records from admission to PICU discharge
2. Nitrogen balance during critical illness assessed using routine dietician calculations from admission to PICU discharge
3. Inflammatory markers (CRP) that relate to the severity of illness, measured using routinely collected blood tests over the PICU stay
4. Muscle wasting and function changes assessed using ultrasound during PICU admission and from PICU discharge to 3 months after PICU discharge
5. Risk factors for PICU-muscle wasting assessed using history and electronic hospital records during PICU stay
6. Length of ventilation, PICU length of stay, and hospital length of stay assessed using electronic hospital records at PICU and hospital discharge
7. Functional physical state (FSS) assessed using FSS score at PICU and hospital discharge and at 3 months
8. Muscle function recovery assessed using Bayley's motor score, MFM 20 or MFM 32 at PICU and hospital discharge and at 3 months
9. Quality of life assessed using PedsQL at 3 months after PICU discharge

Overall study start date
01/09/2020

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Invasively ventilated children (term neonate to 16 years)
2. Expected to stay >48 hours in PICU
3. Receiving some form of nutrition (enteral and/or parenteral)
4. Parents consent to the study
5. Normal neurologically
6. Of walking age
7. Independently ambulatory pre-admission
8. No previous PICU admission within the last 5 years
9. No known neuromuscular disease

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
11/10/2021

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alder Hey Children's Hospital
East Prescott Road
Liverpool
United Kingdom
L12 2AP

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

Sponsor details
Eaton Rd
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United Kingdom
L12 2AP
+44 (0)151 228 4811
emma.rutherford@alderhey.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://alderhey.nhs.uk

ROR
https://ror.org/00p18zw56

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The researchers intend to ensure that their findings impact on children and their families in the future. The results of this study will be presented both locally within the trust, at the UK annual PICU congress (PCCS), the national PICU Study Group (PISG-SG) and European meetings (ESPNIC), then at least two papers will be submitted for publication in a high-impact journal. From this exploratory study examining nutrition to muscle mass loss, it is anticipated that a combined nutrition and rehabilitation intervention may be able to be developed and tested in a future study. This would be in collaboration with the researchers (Scholefield B) undertaking the NIHR HTA-funded PERMIT Feasibility study which aims to determine if an early mobilization intervention is feasible in critically ill children in UK PICUs. The researchers will set up a study Twitter account which will also publicize their research to key parent groups.

Intention to publish date
15/01/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lyvonne Tume (Lyvonne.Tume@edgehill.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	20/07/2021	24/08/2021	No	Yes
Protocol file	version 1	07/05/2021	24/08/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		30/03/2024	19/07/2024	Yes	No