**A prospective observational study to explore the relationships between nuTRition, protein intake ANd muScle mass loss during and after Paediatric Intensive caRE: the TRANSPIRE Study**

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**We invite you to take part in research study**

* As children’s intensive care in the UK has improved in the last decade, almost all children now survive critical illness, but for some, their recovery is prolonged both physically and psychologically.
* Children on the breathing machine in intensive care can lose weight and muscle, and this slows down their recovery and can lead to longer stays both in the intensive care and in hospital.
* Adult research has shown that some of this muscle loss may be able to be lessened by giving patients 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 protein they get.
* We want to find this out and to do this, we want to look at children’s thigh muscles (by ultrasound, so using gel and running a probe over the muscle, which does not hurt at all) when they first come to intensive care, every few days, when they leave intensive care, when they leave the hospital and 3 months later.
* In this study we will use information from your child’s medical records. We will only use information that we need for the research study. We will let very few people know your child’s name and only if they really need it for this study.
* Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.
* At the end of the study we will save some of the data [in case we need to check it] **AND/OR** [for future research].
We will make sure no-one can work out who you are from the reports we write.

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**How to contact us**

**If you have any questions, please contact:**

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Further information can be found on our website:

or Facebook page*:*

**1) Why are we doing this study?**

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 what we want to find out, as children are not the same as adults, and frequently respond in different ways to adults. It is also important for us to understand what happens to the child’s muscles after the child leaves intensive care and the hospital.

**2) Why has my child been chosen?**

Your child has been admitted to Alder Hey Children’s intensive care unit and is on the breathing machine and is being fed into their stomach via a tube.

**3) What will happen if I allow my child to be in this study?**

If you decide to allow your child to participate in this study, one of our researchers (who are children’s intensive care trained specialist nurses, physiotherapists, or a doctor) will ask you to sign a written consent form for the study. Then they will use a special ultrasound machine to look at your 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 your child is admitted to intensive care, and then on day 3,5,7 and 10 if your child stays that long. They will do this both when your 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 we collect about how much food (protein and calories) your child is getting and blood values we can calculate as usual from your child’s daily medical records.

This will allow us 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. We 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. We will also ask you some questions about your child’s activities at various time points and after 3 months (these will be the same questions each time).

If you are coming back to the hospital for any follow up, we will time this 3-month measurement with your hospital visit (and pay for your hospital parking) or you may choose to come back at a separate time for this 3-month visit. If you agree to come back for this 3 month visit after your child’s hospital discharge, we will pay your travel expenses and hospital parking for this visit. For this 3-month visit we will ask you to complete a simple (one average week) diet and activity diary for your child.

**4) Are there any risks or benefits to my child being in this study?**

There are no additional risks to your child from being in this study. The muscle ultrasound is pain free and completely non-invasive. The only burden to you is the extra time required for the 3-month follow up visit, but we will time this with your closest follow up hospital appointment (if you have one) and cover your travel and parking expenses. It is also possible to allow your 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). We cannot guarantee any benefit by your child being in the study.

**5) Do I have to allow my child to take part, and can I change my mind?**

It is entirely up to you whether you allow your child to be in the study. If you do agree to your child being in the study, at any point, should you wish to withdraw them from the study; you are completely free to do so at any time, without giving a reason. This will not affect the care that either you or your child receives in any way.

**6) Does this study affect any of the care they would normally receive?**

No, your child will receive all the usual intensive care and hospital care they would normally receive, with some extra observation of your child’s leg muscle and what nutrition they receive.

**7) Who is involved in this study?**

The National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB) is funding the study. The study has been reviewed by the NIHR RfPB, the University of Salford Ethics Committee, and the Northwest – Liverpool - Central Research Ethics Committee, who have agreed that the study is being conducted in a correct and appropriate manner. Dr Lyvonne Tume (University of Salford, Manchester) is the Study Chief Investigator and a children’s intensive care nurse. The research team are qualified to do this study because they have the specialty knowledge, experience and skills that are needed. Members of team have a lot of experience in caring for children with intensive care and are very active in health research. A child and his father who have experienced being in intensive care have also been involved in the development of this study and are on our study team.

**8) What will happen to the results of this study?**

This study will be presented at conferences and written up for publication in an academic journal, but your child will not be identifiable. We will prepare a lay summary of the results of this study for all parents who have participated, and we will disseminate it via relevant professional social media. We hope that this study will tell us whether more about muscle loss in children during intensive care and how this relates to their nutrition and protein intake so that we can develop an effective intervention to try and target this in a future study.

**9) Will my child’s taking part be kept confidential?**

We will need to use information from your child’s medical records for this research. This information will include your child’s NHS number/name/ contact details of the parent providing consent. We will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know will not be able to see your child’s name or your contact details and as soon as we can, your child’s data will be given a code number instead. Once we have collected the final information about your child at the 3 month follow up, their data will be completely annonymised and we will not be able to identify your child anymore. This annonymised data is kept securely at a secure location by Alder hey Children’s Hospital for 5 years after the study has been completed.

We will keep all information about your child safe and secure and completely confidential and stored only on a very secure password protected computer in the hospital. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study. This complies with the UK regulations around the handling of your child’s data.

**9) What has been done to minimise the risk of contracting coronavirus (COVID-19)?**

As with all clinical procedures in the intensive care unit, all equipment is cleaned and disinfected properly before and after use. All staff wear face coverings at all times indoors and all our staff also have regular weekly lateral flow tests, in addition to being vaccinated. Any patients admitted with unknown coronavirus status are isolated in a separate part of the intensive care unit until a negative COVID-19 test is obtained.

**10) What if there is a problem?**

**Complaints:** Alder Hey Childrens NHS Foundation Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study.  If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Alder Hey Childrens NHS Foundation Trust is at fault.  This does not affect your legal rights to seek compensation. If you are harmed due to someone’s negligence, then you may have grounds for a legal action.  Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator. The normal National Health Service complaints mechanisms are also available to you.  If you want to complain about how researchers have handled your information, you should contact the research team in the first instance. If you are not happy after that, you can contact the Patient Advice and Liaison (PALS) office on Alder Hey Patient Advice and Liaison Services (PALS) services on <https://alderhey.nhs.uk/parents-and-patients/feedback/pals> or phone 0151 252 5374 or 0151 282 4907.