PARENT/LEGAL GUARDIAN INFORMATION SHEET

Nutritional status of children undergoing treatment for Acute Lymphoblastic Leukaemia: Longitudinal observational study

We would like you to think about taking part in our research study. Before you decide, you need to understand why the research is needed and what it would involve.

Part 1 tells you the purpose of this study and what will happen to you.

Part 2 gives you more detailed information about the conduct of the study.

Part 1 - What is the purpose of the study?

The purpose of this study is to observe the impact of leukaemia treatment on nutritional status (the amount of muscle and fat in your body). Changes to your nutritional status throughout treatment may affect how well you recover from treatment. This will be the first study to monitor changes in nutritional status in young people undergoing treatment for leukaemia. The measurements needed to monitor nutritional status will occur when you attend your routine medical appointments at the hospital

Leukaemia is a form of cancer that affects the bones. Our bones make important cells that fight off bugs that can enter our body through our lungs or gut. Therefore, if our bones are not working well this can increase our risk of infections. Long-term survival rates for leukaemia treatment have increased due to advances in medication.

Medical treatment uses chemicals to kill leukaemia cells. The type of medications used in the treatment of leukaemia can alter the amount of muscle and fat levels – this is called sarcopenia. These changes in your muscle and fat levels can reduce your overall energy (calories) requirements. This will be the first study to monitor changes in nutritional status and the impact this has on energy requirements in children undergoing treatment for leukaemia.

Understanding what changes are occurring to your nutritional status during treatment will help to develop guidelines for healthcare professionals to reduce changes and therefore reduce the long-term problems related to a change in nutritional status (obesity, fragile bones and diabetes), and may also help the treatment work better and reduce the risk of having leukaemia again (relapse).

Why have we been chosen to take part? We are inviting all children and young people who have been diagnosed with leukaemia at Great Ormond Street Hospital to take part in this study.

Do we have to take part? No, it is entirely up to you. If you agree to take part, we will then ask you and a parent to sign a consent form. Participation is voluntary and even if you agree to take part, you are free to stop at any time, without giving a reason.

What will happen to me if I agree to take part? We will use different types of equipment to provide researchers with information about your nutritional status (changes to muscle and fat levels).

These measurements will occur when you attend your routine medical appointments at the hospital.

Bioelectrical Impedance Assessment: measure muscle and fat levels. It has 4 leads that are attached to your ankles and wrists and takes 10mins to collect information.

(The picture shows a young person undergoing a bioelectrical impedance to collect information on body composition)

Waist circumference and mid-upper arm circumference (MUAC).

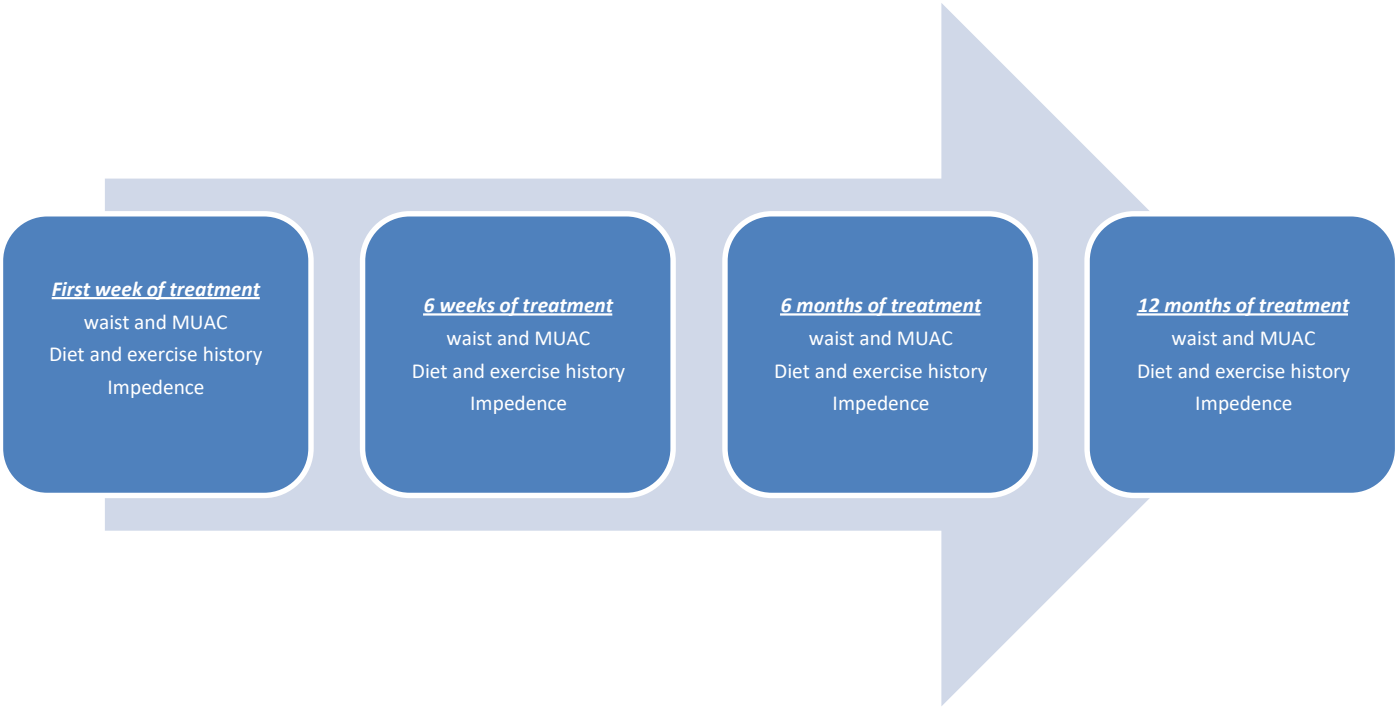
The picture shows a young person undergoing waist and MUAC measurements

Food and Activity Information

To assess if your dietary intake and activity level change over your treatment we will ask you to record your food intake and activity level over 3 days. This will include two weekdays and one day during the weekend.

We will collect this information at 4-time points (see flow chart below) throughout your treatment.

This is a flow chart to highlight the important time points to check your nutritional status



What will we have to do? Your treatment will follow the usual routine medical care. For the study, we will collect the additional measurements to assess your nutritional status as outlined above.

How long will I be asked to take part? 12 months

What are the disadvantages of taking part? Your medical care will be no different if you are not taking part.

What are the possible benefits of taking part? There are no advantages at this early stage of the study, but the results may provide insight and information to identify children who are at greater risk of developing sarcopenia after treatment and therefore ensure appropriate medical and dietetic intervention is accessed.

What are the side effects of the study? All the nutritional status measurements are not painful and classified as non-invasive.

Radiation risk statement

If your child participates in this study, they will have two DEXA X-ray scans. Both will be extra to those you would have if you did not participate. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chance of this happening to you due to taking part in this study is extremely small. The dose of ionising radiation from the X-rays from the two scans is roughly equal to four days of natural background radiation, so it is a minimal dose.

This study requires exposure to ionising radiation in the form of X-rays. All exposures needed for the study are additional to routine clinical care. The total protocol dose is 0.02mSv for two DEXA scans. This is equivalent to approximately 4 days of average natural background radiation in the UK. Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer due to participating in this study is 0.0001%, which is very low. The natural lifetime cancer incidence in the general population is about 50%.

What happens when the research stops? We will collect all the information from all the children, and we will perform an analysis to help understand this complex process. We may use your data for future research or if you lose capacity, we would still like to use your information, which would be unidentifiable.

What if there is a problem? Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in **Part 2**.

Will the research information be kept confidential? Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in **Part 2**.

Who will have access to my medical/research records? Only the researchers involved in this study will have access to your medical records and data collected during this study. The Sponsor and Regulatory Authorities may require access to such data and medical records to monitor and audit the conduct of the study.

We will inform your GP that you are in the study.

We will tell colleagues around the world what we have learned in the study in reports and publications, but nobody will learn anything personal about you. Your name will not appear in any reports or publications. We are following the government's strict rules about how information like this must be stored to keep it secure. We may need to keep the research data for up to 20 years.

Information and data generated from this study may be used to aid future research which will impose the same strict confidentiality process as this study. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they 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. We will make sure no one can work out who you are from the reports we write.

Who should I contact with any questions OR if I want to withdraw from the study?

Thank you for your time and for considering taking part in the study. If you decide to take part, you will be given a signed consent form to keep. If at any point you wish to withdraw from the study please speak with a member of the research team or your care team

If you require further information with regards to the study, please contact:

Contact for further information
Chief Investigator
Dr Graeme O'Connor 0207 4059200 **ext** 5840

Sponsor Organisation*:*

Joint Research and Development Office (R&D*)*

Great Ormond Street Hospital NHS Foundation Hospital

Great Ormond Street

London, WC1N 3JH

Research.Governance@gosh.nhs.uk (please do not send sensitive or personal data)

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2 - more detail – information you need to know if you still want to take part.

What if new information becomes available?
We might get information through more in-depth discussions with you, and this may alter the treatment your child may benefit from. This is not likely, but if the situation does arise, we would like permission to discuss this with your clinical team. If this happens, someone from the research team will tell you about it and discuss it with you. This will not affect your place in the study, but if you do choose to withdraw at any time this will not affect any care you receive whilst in hospital. If you decide to continue in the study you will be asked to sign an updated consent form.

What if there is a problem/Complaint?
If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

If you remain unhappy and wish to complain formally, you can do this through the normal hospital complaints procedure and contact the following person:

Chief Investigator Dr Graeme O'Connor 0207 4059200 ext 5840

Patient Advice & Liaison Manager
Mr Luke Murphy
Great Ormond Street Children's NHS Foundation Trust
Tel: 02074059200 ext 7862
Luke.Murphy@gosh.nhs.uk **or** pals@gosh.nhs.uk

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

at: www.hra.nhs.uk/information-about-patients/

or: Sponsor's Data Protection Officer email: Your.Data@gosh.nhs.uk

or: Great Ormond Street Hospital Privacy Notice: https://www.gosh.nhs.uk/privacy/

or: by asking one of the Research Team

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 2018 and the General Data Protection Regulations 2016 (GDPR).

Your medical notes may also be looked at by other people within the hospital involved in the running and supervision of the study to check that it is being carried out correctly.

Harm: In the unlikely event that something does go wrong, and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation – but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will any extra laboratory or genetic tests be done?
No extra tests outside of those required by your hospital doctors, for clinical reasons, will be done. No genetic testing will be done.

1. What will happen to the results of the research study?
When the study has finished, we will present our findings to other doctors, and we will put the results in medical magazines and websites that doctors read. We would also like to put a summary on the hospital website so that you will be able to read about our results too. Results will also be presented at national and international conferences.

2. Who is organising and funding the research?
The study will be delivered as part of a research degree and will be funded by King Abdulaziz University

3. Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed and given a favourable ethical opinion for conduct with North of Scotland (1) Research Ethics Committee

Who should I contact with any questions?

Chief Investigator Dr Graeme O'Connor 0207 4059200 ext 5840

If you decide to take part in this study, please discuss it with your Parents/Guardian. You will be given this information sheet and signed consent forms to keep.

Thank you for taking the time to read this information sheet.