Will my participation in this study be kept confidential?

During this study your identity will be protected as defined under the Data Protection Act 1998. When you are first registered onto this study you will be given a study number. This study number, along with your initials and date of birth will be used to identify the data we collect.

Only information needed for this study will be collected. All information will be strictly confidential. By taking part in the trial you will be agreeing to allow research staff to look at the trial records, including your medical records and scan images. Your medical records and all data obtained from this study will be made available to representatives of the study Sponsor and regulatory authorities. This is to make sure the information collected is an accurate reflection of the study.

The information collected will be stored on a secure database for analysis at the University of Leeds, and will only be accessed by authorised people, who have a duty of confidentiality to you. Your GP will also be informed so they understand why you will be having some extra tests. You will not be able to be identified in any report, presentation or publication arising from this trial.

What will happen to the results of the trial?

Results may be published in medical and scientific journals, and presented at international conferences, but your name will not be used in any publications. If you would like to obtain a copy of the published results, please ask your doctor or nurse.

Who has reviewed the trial?

This trial has been reviewed by the an independent Research Ethics Committee. Research Ethics Committees review all research to protect the safety, rights, well being and dignity of patients.

What will happen if I don't want to carry on with the study?

You are free to withdraw from this trial at any time without giving a reason and this will not affect your future treatment. If you decide to withdraw you will be asked to allow the continued collection of follow-up data (you will not need to attend more clinic appointments for this than normal for your condition).

Who is organising and funding the research?

This study is funded by Candlelighters charitable foundation and sponsored by the University of Leeds. No-one will receive payment for taking part in this study.

What if there is a problem?

Any concern or complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed. If you wish to complain or are unhappy about any aspect of the way you have been approached or treated during the course of the study, in the first instance please contact your consultant or a member of the research team- you can use the contact numbers at the end of this sheet. If you are still unhappy you can complain through the hospital complaints department.

Local contact for further information

If you require any further information please contact:

Fighting children's cancer CANdle Lighters in Yorkshire

UNIVERSITY OF LEEDS

BONES

British OsteoNEcrosis Study

Patient information sheet for patients aged 16+ years

We would like to invite you to take part in a clinical trial run by the University of Leeds called BONES (British Osteonecrosis Study), which is part of a postgraduate research project. Before you decide whether you want to take part in the study we would like you to understand why the study is being done and what it would involve.

Please take the time to read the following information carefully and discuss it with friends, relatives, doctors and nurses if you wish. Ask us if there is anything that is not clear, or if you would like more information.

You can also visit our website: http://childhealth.leeds.ac.uk/bones.html

V7. 20/11/2017. IRAS 185365

What is the purpose of the study?

You have been diagnosed with Acute Lymphoblastic Leukaemia (ALL) or lymphoblastic lymphoma. The treatment is usually very successful and we are now trying to improve treatment further by investigating the side-effects that can occur during and after treatment, in order to reduce these. One of the side effects that can occur in parts of bone is called osteonecrosis. This happens when there is an interruption to the blood supply to the bone which causes changes in the bone itself, and happens most often in the hips, knees, and ankles. If osteonecrosis is severe patients need surgery. However, in many cases where it is less severe the patient may recover fully.

We know that osteonecrosis occurs more commonly in patients over 10 years of age but we don't know why some people develop it and others do not. With this study we hope to learn more about:

- What makes a person more likely to develop osteonecrosis
- When osteonecrosis develops
- What happens to patients when they develop osteonecrosis

Why have I been invited?

You have been invited because you have been diagnosed with ALL or lymphoblastic lymphoma and are aged between 10 years and 25 years. Over the next 2 years a number of hospitals in the UK will be inviting children and young people diagnosed with ALL or lymphoblastic lymphoma to take part in this trial.

Do I have to take part?

No, taking part is entirely voluntary. It is up to you to decide whether or not you want to take part. You can withdraw at any time, without giving a reason. This would not affect the rest of the care that you receive.

Will anyone else know I'm taking part?

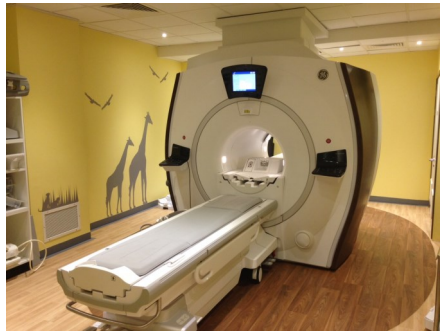
The only people who will know that you are taking part in this study will be the team of doctors, nurses and researchers looking after you.

What will happen if I take part?

Being in the study involves scans, a physiotherapy assessment and a questionnaire. We will also look at your medical records to see the results of some of the tests you are having routinely.

We will look for signs of osteonecrosis by taking pictures of your legs and hips with a special scanner. These are called magnetic resonance imaging (MRI) scans. There will be five scans in total. The first scan will be in the next few weeks. The next scans will be at six months, then one year, two years and three years after you start maintenance treatment. For the scan you will be asked to lie on a table and the table will move through the scanner. It doesn't hurt, and will take around half an hour.

You will also have an appointment with a physiotherapist at roughly the same times as the scan, which will take around 30 minutes. Physiotherapists look at how patients are moving, and they will help us recognise if there are any problems developing with your arms or legs. They will also ask you to complete a questionnaire to see if there seem to be any problems developing.



MRI Scanner

In some centres there will be extra imaging of bones by dual energy X-ray absorptiometry (DXA), which measures bone mineral density and assesses fracture risk . These are routinely performed in some centres, but there is not currently a national standard. We would like to look at the results of these scans, which will be performed at diagnosis and annually, to a total of 4 scans. DXA scans are very safe and painless. You would be required to lie on your side on an X-ray table as a scanner passes over you.

If you agree to take part in this study you will be asked to sign a consent form. You will be a given a copy of it, and this information sheet to keep.

We can reimburse reasonable travel expenses (public transport or car mileage) which are due to being part of this study.

Are there any disadvantages or risks involved in taking part in this study?

If you decide to take part in this trial the leukaemia treatment you receive will be the same as if you choose not to participate.

MRI scans are painless and very safe. They do not involve radiation and there are no known side effects of an MRI scan. There are some cases where an MRI scan may not be recommended, because the strong magnets used during the scan can affect metal implants or fragments in the body. Please let your health care team know if you have any metal in your body. DXA scans use a very low dose of radiation (less than 2 days exposure to normal background radiation), which is much lower than standard X-ray examinations.

There is a possibility we might find something unexpected in your images. If this happens, we will notify you first and you will be referred to the appropriate specialist for further investigation.

Before any trial can start it has lots of safety checks before it can be approved. This study has undergone these checks and we hope that the trial will help improve the treatment for children and young adults with ALL and lymphoblastic lymphoma in the future.

What are the possible benefits of taking part?

The aim of the study is to gain information to improve how we look after young people with ALL or lymphoblastic lymphoma in the future. We are not expecting you to directly benefit from taking part. All the extra tests are only for the study and will not change how you are managed unless something unexpected is seen.

What happens when the trial stops?

At the end of the trial all of the data that has been gathered will be examined, and the results used in the future to help identify patients at highest risk of osteonecrosis, and consider how this risk can be reduced. Anonymised data will be kept for 10 years.

Informed Consent Form (Patient aged 16 years and over)

British OsteoNEcrosis Study

Site_____ Principle Investigator_____

Patient Trial Number _____Trial Reference Number_____

Please initial each box

1. I confirm that I have read and understood the Patient Information Sheet (version 7, 20/11/2017) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care or legal rights being affected. ☐

3. I give permission for a copy of this consent form to be sent to the research team based at the University of Leeds. ☐

4. I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the research team, regulatory authorities, Sponsors and/or NHS bodies, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records and to collect, store, analyse and publish information from this research. I understand that my name will be kept confidential. ☐

5. If I withdraw from the study I agree to allow the continued collection of follow up data. ☐

6. I agree for my GP to be informed about my involvement in this study ☐

7. I agree to take part in the above study. ☐

8. I consent for data from this study to be used in future research projects ☐

Name of patient: _____Date:_____Signature:_____

Name of person taking consent: _____Date:_____Signature:_____