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PIC Bone Parent/Guardian Information Sheet

Information for Adults

Imaging in Paediatric Osteomyelitis (bone and joint infection) (PIC Bone)

What is the role of MRI and ultrasound in the diagnosis of paediatric bone and joint infection?

We would like to invite your child to take part in our research study.

The PIC Bone study is a research study led by surgeons, doctors and scientists who are working to improve accuracy and efficiency of diagnosis of bone and joint infection in children and young people.

We'd like to invite your child to be involved as the clinicians think your child's painful limb may have been caused by bone or joint infection. This is a "cohort study" which means that we would not alter your child's management but just follow your child's condition closely over the next 3 months.
The central study team work at the University of Oxford and the University of Liverpool.
Before you decide if your child can take part, we would like you to understand why the research is being done and what it would involve for you and your child. Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not you give permission for your child's information to be used. Your decision will not affect the care your child receives.

The Facts and the Questions

- Your child has been assessed by the clinicians who believe your child may have a bone or joint infection.
- Serious infections in bones and joints are rare but require urgent treatment (antibiotics) and sometimes surgery.
- Many conditions, other than infection, can cause pain and bone/joint swelling but these often resolve without intervention within a few days.
- The challenge is to quickly identify which child has an infection and which has a different condition.
- Your child's doctor may recommend a variety of assessments/tests to help with their decision about your child's diagnosis. This may or may not include the use of MRI or ultrasound scans.
- This is an observational study, which means we shall closely monitor your child by looking through their medical records over the course of their assessment and treatment without changing any part of the care they receive.
- Your child's details (i.e. NHS number/ Community Health Index (CHI) number, which are unique identifiers) will be kept securely to enable researchers to contact you and your child in three months, to find out more about their experience.

For further information and an animated study explainer video, please scan the QR code for the link to the study website.

The link will also be provided via email or text message. Here is the website URL.

www.picbone.com

How to contact us:
Local Clinical/Research Team details:
Telephone:
PI name and telephone:

PIC Bone_ParentInfo
V2.0_06Feb2024
Mr Tim Theologis
IRAS Project Number: 318114
REC Ref: 23/WM/0027

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What will we find out?

- How helpful ultrasound and MRI scans are in diagnosing the cause of a painful limb in children.
- How we might improve the pathway that clinicians use in the emergency department to more successfully diagnose bone and joint infections.

We cannot guarantee that your child will get any direct benefit from taking part in this study. However, your child taking part will help us improve the way we investigate children with a painful limb, which may lead to better care and outcomes in the future.

This study does NOT involve any <u>extra</u> tests or visits to the hospital!

Why does there need to be a study?

- Approximately 1800 children are admitted yearly to hospitals in England with suspected osteomyelitis (a bone or joint infection).
- Children with acute bone or joint infection present with symptoms of less than two weeks, including pain, reluctance to move the affected limb, raised temperature and malaise. It is important to be able to diagnose bone or joint infections as early as possible to avoid potential bone and joint damage.
- Early differentiation of bone or joint infection from less urgent conditions mimicking the symptoms is critical.
- Diagnosis after history taking, clinical examination, routine blood tests and x-rays can remain uncertain, therefore we would like to understand how helpful MRI and ultrasound scans are in achieving a more accurate diagnosis.

Your hospital is one of many hospitals taking part in this study across the country. We hope to involve as many children and young people with a possible bone or joint infection as we can.

What does the study involve?

- The doctors and their teams at your hospital will collect information about the results of your child's assessments now and in three months (i.e. what assessments they have received, the results of these assessments and the diagnosis your child was given).
- With your consent you and your child will be contacted in three months' time (by email, SMS, or phone) from the research team to find out how your child is doing and whether they received treatment anywhere else. If your child received treatment elsewhere, the research team will inform the original recruiting site and request they seek further information from the relevant non-participating hospital/GP.
- You and your child may also be invited to take part in our sub study exploring your experiences of the clinical investigations your child receives. At this point we would just like to ask for your contact details (name and phone number), child's age in whole years, and whether or not you had a bone or joint infection diagnosis, if consent has been gained, to pass to the team at University of Liverpool conducting the interviews, so they may contact you and explain more.
- **We would also like to be able to contact you and your child in the future about ethically approved research for which your child may be suitable. You would be under no obligation to participate in future studies.**
- There is no payment to patients involved in this study.
- The study results will be made available on the study website when the study is finished.

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

If you do not agree for your child/ to be part of this study, this will not change the care they will receive. You can change your mind at any time and can contact the research team using the contact details on the last page of this sheet.

Consent

We will ask you to sign a consent form, indicating you agree to your child taking part in the study.
To do this, we will send you a link via email and you can agree to participation electronically. Alternatively, you may sign a paper consent form. We don't mind which way you chose!
The consent forms will be stored at the NHS sites.

What if there is a problem?

If you have a concern about any aspects of the PIC Bone study, you should speak with your clinical/research team at your hospital. They will do their best to answer your questions.
PI/RN number again

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity applies in respect of the clinical treatment provided.

If you remain unhappy and wish to complain formally you can contact your local team (details above), or you may contact the University of Oxford Research Governance and Assurance Team office on 01865 616480, or the director of RGEA, email RGEA.Complaints@admin.ox.ac.uk.
The Patient Advisory Liaison Service (PALS)/ Patient Advice and Support Service (PASS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS/PASS is unable to provide information about this research study.

Will taking part in the study be kept confidential?

Yes, only the study team and members of your clinical care team will know about you taking part in the study. When you consent, your personal contact details will be passed to the research team/study management team in Oxford to enable them to contact you in three months to see how your child is doing. This includes your name, email address, and telephone number. A study identification number will be given to each participant when consent is given. All personal information will be stored in a secure database at the University of Oxford. Once we have finished the study, we will keep some of the data, so we can check results. We will write reports in a way that no-one can work out that you took part in the study.

We will be using SMSWorks to process text messages, and their data retention period is 60 days. They are a University of Oxford approved third party service provider to send text messages to you on our behalf. All our third-party service providers are based in the UK and are required to take appropriate security measures to protect your data in line with our policies and in line with GDPR. We do not allow them to use your data for their own purposes. We permit them to process your data only for specified purposes and in accordance with our instructions and we ask that they destroy your data no longer than 60 days after us providing it to them.

If you and your child agree, we would like to retain your contact details until your child reaches 16 years of age, to enable the research team to contact you in future about ethically approved research for which your child may be suitable. If you do not wish to consent to future contact, all identifiable information will be discarded confidentially 12 months after the study ends. Anonymised information (information with only the study identification number) will be kept for 5 years.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Please note that you are responsible for the security of your own electronic devices.

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Who is involved with the study?

- A group of surgeons, doctors and scientists who have many years of experience with working with children and young people in the healthcare setting.
- They work with the Surgical Intervention Trials Unit (SITU) in Oxford who will help manage the project. The SITU team have experience with bone and joint research.
- Generation R (a network of Young People's Advisory Groups) are also supporting the design and delivery of this study.
- The study is funded by a grant from the National Institute for Health and Care Research, an organisation that supports research involving children and young people.
- The study is sponsored by the University of Oxford and has been reviewed by your local hospitals research department.
- We will be using information from you and your child's medical records to undertake this study and will act as the data controller for this study.
- **The study has also been reviewed by the West Midlands-Solihull NHS Research Ethics Committee, who have issued a favourable ethical opinion for the study.**

How will information about my child be used?

UK Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and/or your child's medical records and will use the minimum personally-identifiable information possible. We will keep identifiable information about you up to the point at which your child turns 16 years of age (if you consent to future contact) otherwise any identifiable information will be retained for one year after the study has finished. Research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for (5 years for anonymised information) after the end of the study. However, if you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form until such time as your details are removed from our database but will keep the consent form and your details separate.

The data will be entered into a GCP compliant data collection system. All electronic patient-identifiable information, including electronic consent forms, will be held on a server located in an access-controlled server room at the University of Oxford, accessible only to members of the research team based on their role within the study. The database and server are backed up to a secure location on a regular basis.
All contact will come from the research team in the first instance. However, agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish."

The local NHS Trust/ Health Board will use your details, e.g., name, NHS/CHI number, home address, and contact details to contact you about the research study, send link to consent form and study website, and make sure that relevant information about the study is recorded. A copy of your paper consent form (if applicable) will remain in your medical records for as long as these are held.

UK Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at https://compliance.web.ox.ac.uk/individual-rights.

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