

Kids4LIFe – Assessing Kids for Liver Inflammation and Fibrosis using non-invasive MRI

Information sheet for parents/guardians (of Healthy volunteers)

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

Before you decide whether they should take part, it is important for you to understand why the research is being done and what it will involve. Your child has been given a child-friendly version of this information leaflet. Please take time to read the following information carefully. Please discuss this study with your family, with friends, and your GP if you wish. Part 1 tells you the purpose of this study and what will happen to your child if they take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information.
Thank you for reading this.

Part 1

What is the purpose of the study?

This study aims to find out whether MRI imaging can be used to accurately map the development of the liver, and assess characteristics of other related organs such as the spleen and pancreas.

Why has my child been invited?

We have asked your child to be involved because they are healthy and fit. We need to get images from healthy children so that we know what normal livers, spleens and pancreases look like. We plan to invite at least 30 participants like your child into the study.

Does my child have to take part?

It is up to you and your child to decide whether or not to take part. If your child decides to take part, he/she is free to withdraw from the study at any time without giving a reason. This would not affect the standard of care they receive. If you or your child decide that you no longer wish to continue with the study, we would still keep any data already taken from your child unless you tell us otherwise.

What will happen if my child takes part?

Once we have checked your child is suitable to take part we will invite you and your child to the MRI imaging centre. We will ask your child not to eat or drink for 4 hours before the scan. The entire research visit will take about 45 min per person. At this visit you and your child will have the opportunity to ask any further questions and be asked to complete a consent form.

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Participant information leaflet Parents/Guardians

Ethics Ref:

16/SC/0621

Principal Investigator:

Dr Rajarshi Banerjee

Version/Date:

07/12/16 v2.0

Short Title:

Kids4LIFe

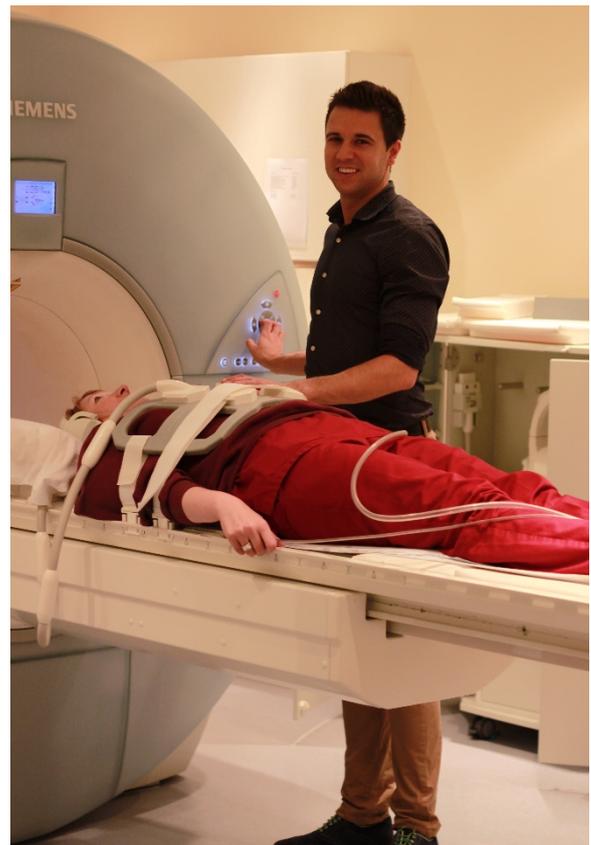
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We will then do the following:

1. Ask some questions about your child’s medical history and whether there might be any reason an MRI scan would be unsuitable for them. If your child is a girl who is over the age of 12, we will need to ask her whether there is any chance that she could be pregnant. If there is a possibility that she might be, she will not be able to participate in the study.

2. Perform a scan of your child’s liver using a magnetic resonance imaging (MRI) machine. The MRI scanner uses a strong magnetic field to create detailed images of the liver, spleen and pancreas and therefore does not use X-rays or any form of radiation. The scan lasts about 15 minutes. Your child will be asked to lie on a table which slides into the scanner. A picture of a scanner is shown. The scanner can be noisy, however we will provide earplugs and/or headphones, and your child can listen to music of your choice during the scan. Some people may feel claustrophobic in the scanner and your child could at any time ask us to stop the scan. If your child wishes, you can be present in the MRI scanning room with your child during the scan.



3. We will collect a standard blood sample. There will be anaesthetic cream available for participants who wish to use it, so that the procedure will not hurt. This is optional, so if for any reason you or your child does not want to donate a blood sample, that is absolutely fine.

Once the visit is over, your child can eat and drink as normal.

If you are happy to, we may ask if you and your child would like to come back for another MRI scan, either in the same clinic or in another clinic so that we can see whether the images of your child’s liver are the same at different times and in different scanners. This is entirely optional.

Will I have any expenses?

We will reimburse you for a light meal for your child (receipts will be required) and travelling expenses.

Are there any possible disadvantages or risks from taking part?

Magnetic resonance imaging does NOT use radiation. It is very safe and there are no known major side effects from the types of scanner that we use. The MRI scan is noisy and we provide earplugs/headphones to protect your child’s ears. The scan also involves lying flat in a slightly confined space and a small number of people find this too claustrophobic. Magnetic resonance could potentially harm an unborn child; therefore if your daughter might be pregnant then she should not take part in this study. If you would like to accompany your child into the scanning room, you will be asked to complete an MRI safety form as well which will ensure that there is no reason (eg. pregnancy, pacemaker or other metallic unfixed implanted device, metallic fragments, extensive tattoos, severe claustrophobia, metal in clothing) why it would not be safe for you to be near the

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MRI machine. Taking blood samples can cause discomfort or a slight bruise. Blood taking is optional for your child.

What are the possible benefits?

There is no anticipated benefit for your child. However, this research programme will hopefully help us to understand more about how to diagnose liver, spleen and pancreatic disease. Results of this research might also lay a foundation for improving and developing new treatment options for children in the future.

What happens when the research study stops?

The research results will be analysed and presented as abstracts at conferences and as scientific research papers. It will not be possible to link any published data to any individual. Further details are included in Part 2.

Will our taking part in the study be kept confidential?

Yes. All the information about your child’s participation in this study will be entered into a secure study database which will be kept strictly confidential. The details are included in Part 2.

This completes Part 1 of the Information Sheet.

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.

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Part 2: further information

What would happen if relevant new information becomes available?

Sometimes during the course of a research study new information becomes available relevant to the research. If this happens, we will tell you and your child and discuss whether they should continue in the study. If there is sufficient evidence to suggest your child may be harmed from taking part in the study, the research study will be stopped.

What would happen if we find anything unexpected on your child's scan?

In the unlikely event of us seeing any other abnormalities on your child's MRI scan, a specialist doctor will discuss this with you and what it may mean for your child. They may arrange for further investigations if necessary. However, it is important to note that we do not carry out scans for diagnosing problems and therefore these scans are not in place of clinical appointment. Our scans are for research purposes only, so if we find anything unusual, it would be appropriate for us to contact your child's GP so that he/she can arrange ongoing care for your child. But we would only do this after we and the specialist had discussed your child's options and gained your permission.

What will happen if your child doesn't want to carry on with the study?

Your child is free to withdraw from the study at any time.

What would happen if something goes wrong or we have a complaint?

Complaints: Any problems connected to the study would be dealt with initially by the researchers conducting the study please contact Dr Kate Groves or Mrs Soubera Rymell on 01865 261457 or clinicalresearch@perspectum-diagnostics.com.

Harm: Perspectum Diagnostics Ltd has appropriate insurance-related arrangements in place in respect of their role as Research Sponsor of this study.

Contacts: If the study researchers cannot answer your concerns, the Chief Investigator and Sponsor may be contacted on Rajarshi.banerjee@perspectum-diagnostics.com

Will your child's taking part in the study be kept confidential?

Some parts of your child's data collected from the study would be looked at by authorised persons from Perspectum Diagnostics, to check that the study is being carried out correctly. All investigators have a duty of confidentiality to your child as a research participant and nothing that could reveal their identity would be disclosed outside the research site. Information that relates to your child will be stored in our secure study database with a unique study code number that is not personally identifiable but will allow us to link together the different types of information.

Participation in future research

We will ask if we can contact you about future studies. This is optional i.e. your child can take part in this study but decline to be contacted again. If you consent, we will keep your child's contact details separately from research data they have provided. Both your child's details and data will carry the same unique ID. This means your child's data is anonymised but that we can "link" details to data. You can withdraw your consent for future contact at any time.

What will happen to the results of the research work?

The results of the work are likely to be published in scientific and medical journals and increase our understanding of how we can diagnose liver, spleen and pancreatic disease. A lay summary of the research study results will be available and we will send this to you if you indicate your interest on

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the consent form. Please be aware that this is the overall anonymised result of the research study and not your child's individual results.

Who is organising and funding the research?

The study is being organised by Perspectum Diagnostics Ltd. The study receives funding as part of the Eurostars-2 programme, project E! 10124 Kids4LIFe.

Who has reviewed the study?

This study was given favourable ethical opinion for conduct by the Oxford Ethics Committee C.

Thank you for taking time to read this information sheet and considering taking part in the study

If you have further questions or would like to register an interest in taking part in the study please Mrs Soubera Rymell or Dr Kate Groves on 01865 261457 or clinicalresearch@perspectum-diagnostics.com.

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Study Code:

Site ID Code:

Participant identification number:

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CONSENT FORM

Kids4LIFe – Assessing Kids for Liver Inflammation and Fibrosis using non-invasive MRI

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated 07/12/2016 (version 2.0) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my child's participation is voluntary and that they are free to withdraw at any time without giving any reason, without their medical care or legal rights being affected.		
3. I understand that relevant sections of data collected during the study may be looked at by individuals from Perspectum Diagnostics Ltd, from regulatory authorities and from the NHS Trust(s), where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's data.		
4. I understand that the information collected about my child may be used in an anonymous form to support other research in the future. It will not be possible for my child to be identified by it.		
5. I understand that anonymised images of my child's body, taken as part of magnetic resonance scans, may be used in research publications. I give consent for future use of images for any publications that may arise from the research.		
6. I understand that this is a research scan that is not useful for medical diagnosis, and that scans are not routinely looked at by a doctor. If a concern is raised about a possible abnormality on my child's scan, it will be discussed with me in the first instance, and if I give permission, my child's GP will be informed.		
7. I agree for my child to take part in this study.		
8. (Optional) I understand why blood samples are being taken, how the samples will be collected, that giving samples for this research is voluntary and that my child or I am free to withdraw our approval for use of the sample at any time without our legal rights being affected. I understand that data collected from the samples will be used in the results of the research study.	YES	NO

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9. (Optional) I agree for my child to donate a sample of blood for this research. I consider these samples a gift to Perspectum Diagnostics Ltd and I understand that neither I nor my child will gain any direct personal or financial benefit from them.	YES	NO
10. (Optional) I agree to be contacted about ethically approved research studies for which my child may be suitable. I understand that agreeing to be contacted does not oblige my child to participate in any further studies.	YES	NO
11. (Optional) I agree for my child's anonymised samples to be used in future research (which may or may not be commercial) here or abroad, which has ethics approval.	YES	NO

Name of Participant

Name of Parent/Guardian _____
Date _____
Signature

Name of Person taking _____
Consent _____
Date _____
Signature

**1 copy for participant; 1 copy for researcher site file;*

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