Repeatability and Reproducibility of Quantitative MRCP

Participant Information sheet

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

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. 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 you if you 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 Magnetic Resonance Imaging (MRI) of the biliary tree (the network of bile ducts within the liver) known as MRCP, gives the same results when it is repeated on the same person after a short break, and when it is performed on the same person in a different MRI scanner.

Why have I been invited?
We have asked you to be involved either because you have a biliary related condition, or because we expect you to have a healthy biliary tree. We need to get images from people with a range of different biliary tree structures so that we can make sure that the results from two different MRI scans are the same in both healthy people and those with all types and stages of biliary-related disease. We plan to invite at least 20 participants with biliary conditions and 20 people without biliary conditions into the study.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw from the study at any time without giving a reason. This would not affect the standard of care you receive. If you decided that you no longer wish to continue with the study, we would still keep any data already taken from you unless you tell us otherwise.

What will happen to me if I take part?
The study will involve having six MRI scans of your biliary tree, also called MRCP scans. Each one will last about 10 minutes. Four of these scans will take place in one imaging centre, and the other two in a different imaging centre located closely to the first. We would arrange transportation between the two imaging centres at no cost to yourself. The entire research visit will take about 3 hours, but you will only be in the scanner for about 60 minutes in total.

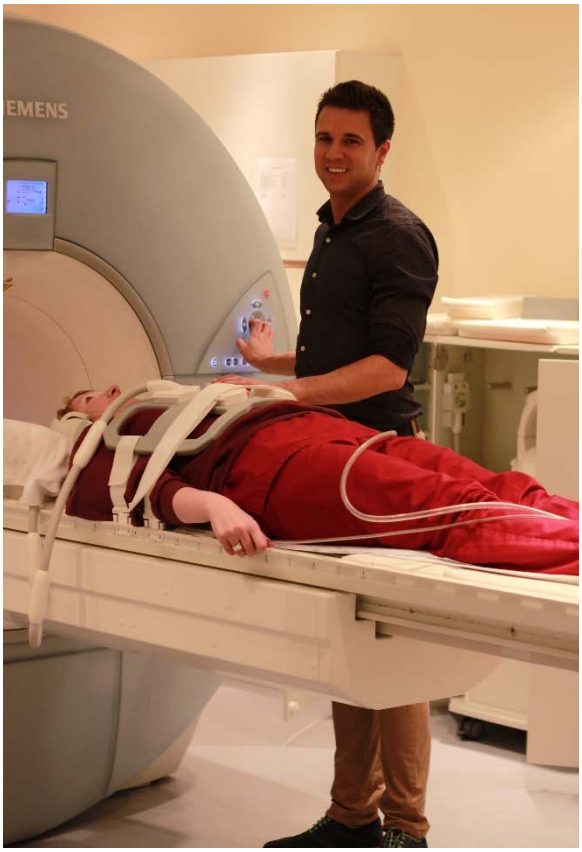
Once we have checked you are suitable to take part we will invite you to the Imaging Centre. We will ask you not to eat or drink anything for 4 hours before the visit. At this visit you will have the opportunity to ask any further questions and be asked to complete a consent form.

We will then do the following:

1. Ask some questions about your medical history and whether there might be any reason an MRI scan would be unsuitable for you.

2. You will be given a carton of pineapple juice and asked to drink this 15 minutes prior to your scans. The pineapple juice contains manganese which helps to give better pictures during the scan.

3. Perform a scan of your biliary tree using a MRI machine. The MRI scanner uses a strong magnetic field to create detailed images of the biliary tree and therefore does not use X-rays or any form of radiation. The scan lasts about 10 minutes. You will be asked to lie on a table which slides into the scanner and breathe normally. A picture of a scanner is shown. The scanner can be noisy, however we will provide earplugs and/or headphones, to wear during the scan. Some people may feel claustrophobic in the scanner, if this happens to you at any time you can ask us to stop the scan. You may also feel some warmth during the scan, but this is normal and nothing to worry about.



4. Take you out of the scanner for a short break before putting you back into the scanner again for a second identical scan.

5. Take you to a second scanner where you will receive two more MRI scans, each lasting about 10 minutes with a short break in between.

6. Arrange transportation to a second imaging centre near the imaging centre in which you were just scanned.

7. Take you to a third scanner where you will be asked to drink some more pineapple juice and will receive two final MRI scans, each lasting about 10 minutes with a short break between. You will need to fill out a second safety form before being scanned at the second site.

8. Arrange transportation back to the first site, if needed.

Some people will have their first 4 scans at the Oxford Centre for MRI (OCMR) and then move on to the Churchill Imaging Centre, while others will have their first 2 scans at the Churchill Imaging Centre and then move on to the Oxford Centre for MRI. We will make it clear which centre you need to arrive at first.

Once the visit is finished you will be able to eat and drink again as usual.

Will I have any expenses?
We will reimburse you for travelling and accommodation expenses and those of a companion if you would like someone to accompany you. We will also reimburse your expenses for a light meal (receipts will be required). A single payment of £100 on top of these expenses will also be offered as a thank you for participating in the study.

Are there any possible disadvantages or risks from taking part?
Magnetic resonance imaging does NOT use radiation. MRI scans are 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 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, you should not take part in this study if you are pregnant or think you might be. As part of the study you will be asked to drink pineapple juice, if you are allergic to pineapple juice, or have any reason why you cannot consume pineapple juice, you should not take part in this study.

What are the possible benefits?
There is no anticipated benefit for you. However, this research programme will hopefully help us to understand more about how to measure changes in biliary diseases. Results of this research might also lay a foundation for improving and developing new treatment options available 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 my taking part in the study be kept confidential?

Yes. All the information about your 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.

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 discuss whether you should continue in the study. If there is sufficient evidence to suggest you 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 scan?
In the unlikely event of us seeing any other abnormalities on your MRI scan, a specialist doctor will discuss this with you and what it may mean for you. 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 GP so that he/she can arrange ongoing care for you. But we would only do this after we and the specialist had discussed your options and gained your permission.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time.

What would happen if something goes wrong or I 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 Mr Andy McKay on 01865 655343 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 Dr Rajarshi Banerjee may be contacted on Rajarshi.banerjee@perspectum-diagnostics.com or the sponsor Dr Jaco Jacobs may be contacted on jaco.jacobs@perspectum-diagnostics.com

Will our taking part in the study be kept confidential?
Some parts of your 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 you as a research participant and nothing that could reveal your identity would be disclosed outside the research site. Information that relates to you 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. you can take part in this study but decline to be contacted again. If you consent, we will keep your contact details separately from research data you have provided. Both your details and data will carry the same unique ID. This means your 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 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 the consent form. Please be aware that this is the overall anonymised result of the research study and not your individual results.

Who is organising and funding the research?
The study is being organised Perspectum Diagnostics Ltd and funded internally by Perspectum Diagnostics Ltd.

Who has reviewed the study?
This study was given favourable ethical opinion for conduct by the South Central – Oxford C REC.

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 Mr Andy McKay or Dr Velicia Bachtiar on 01865 655343 or clinicalresearch@perspectum-diagnostics.com.

Study Code: *Site ID Code:* *Participant identification number:*

CONSENT FORM

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Name of Researcher: *If you agree, please initial box*

1. I confirm that I have read the information sheet dated 04 Aug 2017 (version 1.0) 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 participation is voluntary and that I am free to withdraw at any time without giving any reason, without my 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, and from regulatory authorities where it is relevant to me taking part in this research. I give permission for these individuals to have access to my data.	
4. I understand that the information collected about me may be used in an anonymous form to support other research in the future. It will not be possible for me to be identified by it.	
5. I understand that anonymised images of my 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 scan, it will be discussed with me in the first instance, and if I give permission, my GP will be informed.	
7. I agree to take part in this study.	

Please tick and initial:

8. (Optional) I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.	☐ YES	☐ NO

_____	_____	_____
Name of Participant	*Date*	*Signature*
_____	_____	_____
Name of Person taking Consent	*Date*	*Signature*

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