



Patient Information Sheet

Magnetic resonance imaging to enhance the diagnosis of fetal developmental brain abnormalities in utero. MERIDIAN Add on study

Thank you for your interest in this research. We would like ask you to take part in a research project which uses new methods of looking at a baby's brain while still in the womb. The project involves magnetic resonance imaging (MRI), which is a type of scan already used in many hospitals for other reasons both in and out of pregnancy. Please read this information sheet carefully and if there is anything that is not clear or you need more information, please do not hesitate to ask us. Even if we cannot speak to you immediately, one of our team will get back to you.

Why is the project happening?

Ultrasound scanning is universally used during pregnancy. Although ultrasound is good, no medical test is perfect and in some cases ultrasound does not give all the information needed to make a full assessment of the unborn baby's brain development. MRI has been demonstrated to be better at looking at some aspects of the developing brain. We are currently trying to identify how much better MRI is than ultrasound.

The aim of the project is to find out how and when MRI should be used to improve the information available to parents before birth about the health of their baby. In this part of the project we are looking at babies whose brains are developing normally. We are going to see if ultrasound and MRI give the same information about brain development. The research is set up to look at brain development only and any investigations used by us focus on this area alone.

Why have I been chosen?

You have been asked about taking part because you have recently had a detailed antenatal brain ultrasound which showed your baby's brain was developing normally. Please don't be worried that there are any concerns about your baby's brain - we are just checking that an MRI scan could be used as well as or instead of an ultrasound to give the same information.

Do I have to take part?

No, your taking part in this study is voluntary. You may decide not to take part. If you decide to take part, you will be given this information sheet to keep, and you will be asked to sign a written consent form.

You can still withdraw at any time. You do not have to give a reason if you withdraw from the study, this will not affect your medical care.

What will happen to me if I take part?

If you decide to take part, we will contact you to ask some routine questions to make sure that MRI is a safe procedure for you. If you have a heart pacemaker, you have had previous brain or heart surgery, or you have suffered an injury to your eye (such as a metal splinter) you should inform us so we may check this before the MRI takes place. We will arrange a date for your scan. When you come in for the scan we will also take your written consent to take part.

The MRI will take place at the Academic Unit of Radiology in the Royal Hallamshire Hospital in Sheffield. You will be seen by a member of staff in the MRI department before your scan and they will explain to you what will happen during the scan. You will also be able to ask questions before and after the scan takes place. The MRI scan normally takes around 30 minutes in total, although this may be longer if you are carrying twins or if your baby is particularly active during the scan. You will be asked to lie very still. During the scan you will hear the loud noise made by the MRI scanner while it is working. You will be given earplugs or headphones before the scan starts to reduce this noise. Some people may feel enclosed inside the scanner, and possibly experience feelings of "claustrophobia", so you may wish to have another person present in the scanner room with you (for instance your partner, a close relative or friend). This is OK as long as they complete a visitor safety questionnaire so that we know they are safe to enter the scanner room.

Extra Options

If you agree we would like to be able to use some of the pictures, or "images", from your scan for teaching purposes or where appropriate in other publications relevant to this research. None of your personal details would ever be printed on these images. We may also wish (which is included on the consent form) to contact you regarding future studies into your child's development.

It is entirely your choice whether you agree to the use of images for teaching purposes, or take part in any future studies as your child grows. It will not affect your care you receive if you decide not to take any of these options.

What are the possible disadvantages and risks of taking part?

There are no known problems regarding the use of MRI scanning in pregnant women. Some people can find being in the MRI scanner uncomfortable or unpleasant. It is important to point out though that most people experience little or no problem at all when they are having their MRI scan.

It is possible that the information from your MRI scan might be different from the information shown on your ultrasound scan. This can happen because no single medical test is perfect, and sometimes information provided by tests such as ultrasound and MRI may be incomplete or difficult to interpret. We know this could be worrying for you. We will make sure your GP and consultant at your hospital have the information so they can talk to you about what it might mean.

What are the possible benefits of taking part?

Researchers, doctors and other health care professionals who are involved in scanning babies before birth could benefit from this research by gaining a better understanding of how and when to perform MRI scans for pregnant women. In the future, pregnant women who have been told their baby might have a problem could benefit from the results of this research.

You will also be offered an MRI picture of your baby to keep, and a £10 voucher.

Will my taking part in this project be kept confidential?

All data obtained in the study will be kept confidential. All information provided by you or recorded by the research team will be kept under code number. Data will be made available only to the research team staff, your GP and consultant (if you have one). All information will be kept in a locked room at the Academic Unit of Radiology in the University of Sheffield, within the hospital clinic or radiology department where your MRI scan takes place. Copies will also be stored in a locked room and on a secure electronic database at the University of Sheffield School for Health and Related Research (SchARR).

Will I get travel expenses?

We will be able to pay reasonable travel expenses for your travel to Sheffield for your MRI scan. If you bring a partner, relative or friend their travel costs will also be covered.

What will happen to the results of the research project?

Researchers may present the results of this project in research conferences, or they may publish in scientific or medical journals. None of your personal details will be identifiable.

What if something goes wrong?

Since there are no known health risks specifically associated with this study, it is very unlikely that you will be harmed as a result of taking part. In the 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 legal action for compensation against the University of Sheffield. You may however have to pay your own legal costs. The normal National Health Service complaints procedure will still be available to you.

What if I wish to make a complaint?

If you wish to raise a complaint about the way you have been dealt with, or about any harm you feel you have suffered, you can contact Professor Paul Griffiths (see contact details below).

Alternatively, you can contact the Patient Service Team at the Royal Hallamshire Hospital at: Patient Partnership Department, B Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, South Yorkshire, S10 2JF, tel: 0114 2712400 or via e-mail: PST@sth.nhs.uk.

Involvement of general practitioner (GP)

We will write to your GP to let them know that you are taking part in this study.

Who is organising and funding and reviewing the research?

This research is being carried out by the University of Sheffield and is funded by the National Institute for Health Research (NIHR), which is a part of the NHS involved in medical research. The research has been approved by South Yorkshire Research Ethics committee (reference: 11/YH/0006).

The doctor who oversees the MRI scan will not be paid specifically to perform the scan and therefore he/she has no conflict of interest in your care.

Contact for further information

If you would like further information about the study, please contact Professor Paul Griffiths:

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Thank you for taking the time to read this information sheet