St George's University Hospitals NHS
NHS Foundation Trust
St George's Healthcare NHS Trust
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PARTICIPANT INFORMATION SHEET- Pregnancy Recruitment
FOLD Study
Fetal Oedema and Lymphatic Disorders Study
Chief Investigator- Professor Sahar Mansour
IRAS ID: 259711

Part 1 of the Information Sheet

Study title
An Investigation into the aetiology and genetics of fetal oedema/hydrops

Invitation
We would like to invite you to take part in our research study, which is designed to increase understanding about fetal hydrops/oedema and discover new genetic causes. Before you decide, it is important for you to understand how the research is being done and what it will involve for you. Please take time to read the following information carefully. Ask us if anything is unclear, or if you would like more information. Take time to discuss this with your relatives and family doctor if you wish before you decide whether or not to take part.

One of our team will go through the information sheet with you and answer any questions you have. This should take about 10 minutes. (Part 1 of the Information Sheet tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you further information about the conduct of the study).

Thank you for reading this information sheet.

What is the purpose of the study?
Fetal hydrops and oedema (swelling) describe the abnormal accumulation of fluid in a baby during pregnancy. There are many different reasons fluid can accumulate including infection, structural problems, such as congenital heart disease, and genetic disorders. Sometimes we are unable to determine the cause of the oedema or hydrops. Depending on the cause, sometimes the fluid goes away, and the baby gets better. However sometimes oedema and hydrops are a sign that the baby is very unwell. It can be difficult to diagnose the cause of oedema in an unborn baby and predict the outcome. We request your help to learn more about this condition, including the identification of new genes and finding ways to better diagnose the cause of the oedema during the pregnancy.

Why have I been invited?
We have approached you because your baby is affected by oedema and/or fetal hydrops.

Do I have to take part?
This decision is up to you entirely. If you do decide to take part, please keep this information sheet. You will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?
No additional visits or consultations are required for you to take part in this study. We would like your help with the following:

(i) To allow researchers access to your medical records to document (anonymously) the results of medical, pregnancy and genetic investigations.
(ii) We may ask your ultrasonographer to make additional measurements during the course of the next or subsequent planned ultrasound scan. These would be routine measurements, but which may not usually be performed at that gestation or may not usually be considered clinically relevant. It is estimated that this may add a few extra minutes to an ultrasound scan but would not cause any discomfort or harm to mother or baby.
(iii) In some cases we would like to follow up after the pregnancy has concluded. For some babies this will mean recording their condition at birth (from medical records). We would then like to contact you (by telephone) at 3 months, 6 months and 1 year post delivery to document your baby's progress. This would involve answering some simple questions about your baby's development and medical health, and would be anticipated to take between 10 and 20 minutes.
(iv) In those cases where parents have made the difficult decision to terminate a pregnancy or the baby dies before, during or after birth we request your permission to access post-mortem investigations.

In addition, for those pregnancies where the cause of the oedema/hydrops is unknown we would like your help with:

(i) Allowing us to undertake, analyse or re-analyse your genomic testing.
a. Genomic testing involves analysing DNA for mistakes in the 'spelling' of genes (i.e. mutations). In this way we may find mistakes, which are the cause of the hydrops/oedema or we may find no significant mistakes. We may find changes in the gene, which we are unable to fully interpret. These are called Variants of Unknown Significance (VUS). You may be aware that with NHS genomic testing there is the potential to identify predisposition to other health conditions (incidental findings). In this study we are not looking for those unrelated predispositions and will not report these to you or your doctors should we find them. We will only report those gene mistakes, which we strongly believe to be the cause of the oedema or hydrops.

Where initial testing does not identify a mistake in a known hydrops gene, we may continue to re-analyse that sample for 2-3 years as we learn more about the significance of new hydrops genes.

Should we find a gene mistake that caused the fetal hydrops in you or your baby we will notify you and your referring clinician. Your referring clinician, who may wish to have the result checked in an NHS accredited laboratory. We will ensure you are referred for appropriate genetic counselling, where this is not already in place. We can provide a letter that other family members, who are at risk, for example siblings, and children, can take to their GP to seek referral to Clinical Genetics.

With your written consent any leftover DNA sample from this study will be stored safely by the research team and could be used in future research projects on fetal oedema/hydrops pending ethical approval being obtained at the time.

We will inform your GP that you have kindly agreed to participate in this study.

Are there any side effects of giving a blood sample?
Almost all individuals involved in this study will have stored DNA through their NHS testing. For those individuals requiring a new sample of blood this procedure involves momentary pain and may leave a small bruise.

What are the possible disadvantages and risks of taking part?
There are no disadvantages or risks of taking part other than that mentioned above momentary discomfort at the site of blood sampling where applicable. The disadvantages of genetic testing such as the potential to find variants of unknown significance and incidental findings are described above.

What if there is a problem?
The NHS Trust has full indemnity cover in the event of a claim on or on behalf of, a subject for non-negligent harm. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

What are the possible benefits of taking part?
We hope to better understand fetal oedema and hydrops. This study will provide information which will help clinicians diagnose the cause of a baby's oedema and provide a better prognosis. In the future we hope that accurate diagnostic information will be useful to those developing treatments for fetal oedma.

In some cases, we may identify a genetic cause of the oedema which affects your baby. This would provide you and other family members with useful information about recurrence risk.

Will my taking part in the study be kept confidential?
St George's University Hospitals NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. St George's University Hospitals NHS Trust will keep identifiable information about you for up to 5 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner.

St George's University Hospitals NHS Foundation Trust will use your name, contact details and other identifiers to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from St George's University Hospitals NHS Foundation Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in St George's University Hospitals NHS Trust who will have access to information that identifies you will be people who need to contact you to as part of the research study you are involved in, and or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

St George's University Hospitals NHS Foundation Trust will collect information about you for this research study from your medical records. If you are a patient at Kings College Hospital NHS Foundation Trust, information collected from your medical records will be passed on to St George's University Hospitals NHS Foundation Trust. This information will include your name, date of birth, NHS number and health information, which is regarded as a special category of information. We will use this information to complete this research and let you know about the results of our research if you wish to be informed

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.
Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Your rights to access, change or move your information are limited, as we need to manage the data in specific ways to ensure the research we conduct is reliable and accurate. If you withdraw your consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about you that we have already obtained to ensure research integrity is maintained in the public's interest. To safeguard your rights, we will strive to use the minimum personally-identifiable information possible.

You can find out more about how we use your information
https://www.stgeorges.nhs.uk/about/privacy-notice/

For general information on how the NHS uses research data please visit
https://www.hra.nhs.uk/information-about-patients/

This completes Part 1. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2 of the Information Sheet

What if relevant new information becomes available?
Sometimes new information about a disease or its treatment becomes available. This research study is aimed at improving our understanding of fetal oedema and hydrops. If further information did become available, it is unlikely that this could have any bearing on how the study is being conducted.

What will happen if I don't want to carry on with the study?
You can withdraw from the study at any time. If you decide to withdraw, we would still like to use any data we have already obtained. This would not affect your medical care.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (telephone ********** for Dr Esther Dempsey or esther.dempsey@nhs.net). You could also obtain advice from the Patient Advice and Liaison Service (PALS, telephone 020 8725 2453, e-mail pals@stgeorges.nhs.uk). In the event that something goes wrong and you are harmed during the research, and that this is due to someone's negligence, then you may have grounds for a legal action for compensation against St George's Healthcare NHS Trust, but you may have to pay your own legal costs. The normal National Health Service complaints mechanisms will still be available to you. NHS Indemnity does not offer no-fault compensation (this means it does not offer compensation for harm where there is no negligence involved) and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm, but they are able to consider an ex-gratia payment in the case of such a claim.

Involvement of your General Practitioner (GP)
We will let your GP know (by letter) that you are taking part in this study. If there are any clinically significant findings, we would like to inform you GP, but this will only be done with your consent.

What will happen to the results of the research study?
We plan to write papers in medical journals explaining to others what we learn from our studies. Your identity will not be revealed in any such publications. Study participants who would like to receive a written summary of our findings can do so by contacting Dr Dempsey (contact details below).

Who is organising and funding the research?
Dr Esther Dempsey, Dr Pia Ostergaard, Dr Malou Van Zanten, Professor Sahar Mansour and Dr Tessa Homfray, are organising the research. Professor Mansour is in overall charge of the clinical side of the project. The British Heart Foundation has funded the study.

Who has reviewed the study?
……. Research Ethics Committee. REC reference:

Contact for further information
Should you wish to discuss any issues pertaining to this study please contact either:
Dr Esther Dempsey
St George's Healthcare NHS Trust

Blackshaw Road
London SW17 0QT
Telephone
e-mail esther.dempsey@nhs.net

or: sahar.mansour@nhs.net

Thank you for considering this.