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Participant Information Leaflet

Intramural pregnancy registry

There is a lack of good quality research on Intramural pregnancy, making it difficult to fully understand the condition. This study aims to learn more about how the condition develops and the different treatment options available.

We would greatly appreciate you reading through this information sheet before you decide whether or not you would like to consider taking part. This information is to ensure you fully understand your involvement.

Thank you for your time!

WHY IS THIS STUDY BEING DONE?

Intramural pregnancy is a rare type of ectopic pregnancy, and there is very little information available about how to diagnose, treat, or understand its progression. Ectopic pregnancies, happen in about 1-2% of pregnancies, with over 90% of them occurring in the Fallopian tubes. However, only around 100 cases of Intramural pregnancy have been reported, making it challenging to study.

Right now, there is no clear treatment guideline for managing Intramural pregnancies, and we also have limited knowledge about how this condition might affect future pregnancies. To help doctors and patients make informed decisions, it is important to gather more evidence on the best ways to diagnose and treat this condition.

WHAT IS THIS RESEARCH PROJECT ABOUT?

We propose creating an international registry for Intramural pregnancy cases. This registry will collect anonymous information about how the condition is diagnosed, how it progresses, and how it is treated. By gathering data from a larger number of cases, we can better understand this rare type of ectopic pregnancy. The information collected will help us develop standard guidelines for diagnosing and treating Intramural pregnancies in the future.

OUR AIMS

The purpose of this study is to enhance understanding of Intramural pregnancy, including its diagnosis, associated risks, and the most effective treatment options.

WHY HAVE I BEEN APPROACHED?

You have been approached for the study as you have been diagnosed with an Intramural pregnancy.

WHAT HAPPENS IN THE STUDY?

By agreeing to participate, you permit your doctor to add information related to your diagnosis, ultrasound exams, medical history, treatment, and any potential complications to the study registry. All collected information will be kept strictly confidential. The data in the registry will be anonymised, ensuring that no identifying details, such as your name or address, are included. Your personal data will be removed from the registry and held in a separate secure system, linked with a unique identifier. Participation requires no further action from you. Your data will be stored in a secure, web-based system accessible only to the study team. Your data will be held within the EU and will not be exported from there.

DO I HAVE TO TAKE PART?

No. It is up to you to decide whether you want to be part of this study. Deciding not to take part will not affect the healthcare that you receive, or your legal rights.

WHAT ARE THE BENEFITS OF TAKING PART?

You may not benefit directly from this study, but the information we collect will help us better understand Intramural pregnancies and therefore improve health care for people diagnosed with Intramural pregnancies in the future, which you may find rewarding.

ARE THERE ANY RISKS OF TAKING PART?

Participation in this study does not carry any direct risks to you. Your information will be kept secure, and only your doctor will have limited access to upload your data to the study registry. The study team will be able to view this data to conduct the study, but no one else will have access to it.

WHAT IF I NEED HELP OR SUPPORT?

If you need support with any physical symptoms you should get in touch with the Early Pregnancy Unit. If you need any long-term psychological support, we advise you contact your GP to discuss how you are feeling and/or contact an independent support organisation. The Ectopic Pregnancy Trust provide information and support to women who have experienced ectopic pregnancies or any other form of early pregnancy loss. They can be contacted on their helpline number: 020 7733 2653 or you may want to visit their website: http://www.ectopic.org.uk.

YOUR CONFIDENTIALITY AND DATA PROTECTION

The data generated from the contact points with you will be kept anonymously within the hospital in a secure location entirely separate from your hospital notes. We will not pass this information

to any other party. UCLH will use this information to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals and regulatory organisations may look at your medical and research records to check the accuracy of the research study. 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. All information collected about you during this study will be confidential.

We will need to use information from your medical records for this research project. This information will include your year of birth and ethnicity. The only people who can use this information are people who are authorised to do so. Your data will be stored with a code number. People who do not need to know who you are will therefore not be able to see your name or contact details. The data will be stored in a dedicated folder in a locked cabinet in Clinic 3, Lower Ground Floor, Elizabeth Garrett Anderson Wing, 235 Euston Road, NW1 2BU.

Data will be stored and analysed in compliance with the Data Protection Act. Data will be archived for a minimum of 20 years after the completion of the study before being deleted, in accordance with current NHS regulations. Participants who chose to withdraw their consent will be withdrawn from the study. Data already collected with consent would be retained and used in the study. Only members of the medical staff involved in your care and the direct research team will have access to your data.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk.

Your personal data (year of birth and ethnicity) will be processed so long as it is required for the research project. We will anonymise or pseudonymise this personal data and will endeavour to minimise the processing of personal data wherever possible.

The lawful basis that will be used to process your personal data is: 'public task' and 'research purposes' for processing special category data. The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. This is because we need to manage your records in specific ways for the research to be reliable. It also means that we will not be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHAT WILL HAPPEN IF I DO NOT WANT TO CARRY ON WITH THE STUDY?

Your involvement in this study is voluntary, as is the option to withdraw from the study at any point. If you do not want to carry on with the study, please inform the study team (on the contact details provided at the end of this document), and your standard of care will not be affected in any way. Any data already collected with your consent will be retained and used in the study. No further data will be collected after your withdrawal from the study.

WHAT IF SOMETHING WENT WRONG?

In the unlikely event that you feel you have been harmed by taking part in this study, or have any other concerns regarding the study, please speak to a member of the study team. If you remain unhappy or wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the research team, or the Patient Advice and Liaison Service (PALS) can be accessed by visiting the UCH office Monday-Friday 9am–4pm, or by telephone, 02034473042, or email uclh.pals@nhs.net.

WHAT WILL HAPPEN TO THE FINDINGS OF THE STUDY?

This study is part of a research project. The findings of the study will be published on publicly accessed websites and research journals. If you wish to receive a copy of the findings, please do not hesitate to contact simrit.nijjar@nhs.net. The findings of the study will be available after sufficient data has been collected and the findings published. This may take several years.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research is being organised by Dr Simrit Nijjar. This study will form part of a PhD academic qualification for Dr Simrit Nijjar who is studying at UCL academic institution.

WHO HAS REVIEWED THE STUDY?

All proposals for research involving human subjects are reviewed by an Ethics Committee before they can proceed. This study was reviewed by South Central - Oxford C Research Ethics Committee; their aim is to protect people who take part in research.

If you would like to discuss any aspects about this sheet further or if you have any questions about taking part in the study, please contact:

Student Research Investigator:	**Dr Simrit Nijjar**
Tel:	020 3447 6515 (please leave a voicemail)
Email:	**simrit.nijjar@nhs.net (please use IMP Registry in the heading)**
Address:	**Early Pregnancy Unit, University College Hospital London, 235 Euston Road, London, NW1 2BU**

Dr Simrit Nijjar, Student researcher, Principal investigator

Prof Davor Jurkovic, Gynaecology Consultant, Academic supervisor & Chief Investigator