

STUDY TITLE: Body Composition and effects on the Reproductive Tract

You have been invited to take part in our research study. Before you decide whether you wish to take part, it is important for you to understand why the research is being done and what it will involve.

Please take ample time to read the following leaflet carefully and discuss with friends, relatives or your GP. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether you wish to take part.

What is the study about?

During conception, the egg travels down the Fallopian tube where it gets fertilised by sperm and the fertilised egg (which forms the embryo) continues the journey towards the womb. For a pregnancy to occur, implantation of the embryo into the mother's womb has to occur in order to gain access to nutrients needed to grow. The embryos' environment, which includes the fluid inside the womb the womb lining can be influenced by what the mother eats.

The aim of this study is to assess the impact of maternal diet and pregnancy history on the reproductive tract, and whether certain components of the embryo's surrounding such as tissue structure and communication between different cells in the reproductive tract are indeed affected. From this, we can better understand the origins of reproductive disorders such as subfertility or miscarriages.

Do I have to take part?

No - taking part is voluntary. If you do decide to take part, you can withdraw from the trial at any time, without providing a reason. This will not affect your care in any way.

What will happen to me if I take part?

We will ask you some questions to make sure that it is safe for you to take part in the trial and this will include questions about your medical history and any medications you are on. Once we know it is safe for you to take part, you will be asked to sign a consent form by a member of the research team. If you are not eligible to take part, you will not enter the trial and your care will return to your usual doctor.

You are eligible to take part if:

- You are female and aged ≥ 18 and ≤ 45 years
- No chronic illness that influences fertility, e.g. diabetes or autoimmune disorders
- Not on hormonal contraception

If you are eligible and agree to take part, then we would ask you to complete a questionnaire which should take no longer than 15 minutes. We would be looking to take a blood sample and a sample of the fluid / lining of the womb (endometrium), at a specific time in your menstrual cycle. You will be asked to monitor your menstrual cycles and inform us on whether your cycles are regular or not. Where possible, you will be supplied with ovulation sticks to determine whether ovulation has occurred. When ovulation has been detected, we would like you to inform the research team (contact details at the end of this sheet) so that an appointment can be made for the blood and tissue sample to be taken 8-10 days after this.

The endometrial sample (tissue and/or fluid) will be obtained using a fine tube which is inserted inside your womb. This procedure is quick, safe and sterile and is commonly performed by clinicians in clinic. In some cases, we may ask for a sample of your menstrual blood; we will provide the equipment and instructions for how to collect your menstrual flow where appropriate.

If you are undergoing a surgical procedure as part of your treatment that involves the removal of your Fallopian tube(s), we may also ask for a sample of your Fallopian tube(s) to be taken for research purposes.

What are the possible disadvantages and risks of taking part?

There are no long term disadvantages or risks of taking part. During the sampling of the endometrium, you may experience some temporary discomfort or pain, similar to a 'period cramp'.

What are the possible benefits of taking part?

By taking part, it is unlikely that the findings will benefit your health directly. However, the information we get from this study will improve our understanding and possible treatment of disorders of reproduction such as subfertility or miscarriages.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the clinical researchers who will do their best to answer your questions (details at the end of this leaflet). If you remain unhappy and wish to complain formally, you can do so through the NHS Complaints Procedure.

Will my taking part in this study be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. You will be allocated a unique code and your responses to questions will be held in a coded form in a secure central database which is only accessible to the research team. Your responses will not be identified when the results of the study are published. However, we do ask permission to contact your GP to let them know that you are taking part in the study.

What will happen to the results and samples of the current research study?

The results of this study will be published e.g. in peer reviewed medical journals, reports and textbooks. The anonymised data will be stored for five years at the University of Southampton and may be considered for possible use in future ethically approved projects related to the womb environment.

Who is organising and funding the research?

The research is being led by Dr Bonnie Ng (MRC Clinical Research Fellow) and Professor Ying Cheong, Professor of Reproductive Medicine at University of Southampton. This trial is sponsored by the University Hospitals NHS Foundation Trust. This study has been given a favourable ethical opinion for conduct in the NHS by Southampton and South West Hampshire Research Ethics Committee.

Contact Details

You may contact our clinical research team directly by emailing for further information. Contact: Dr. Bonnie Ng, email: bonnie.ng@soton.ac.uk or Professor Ying Cheong, email: Y.Cheong@soton.ac.uk

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