POPPY

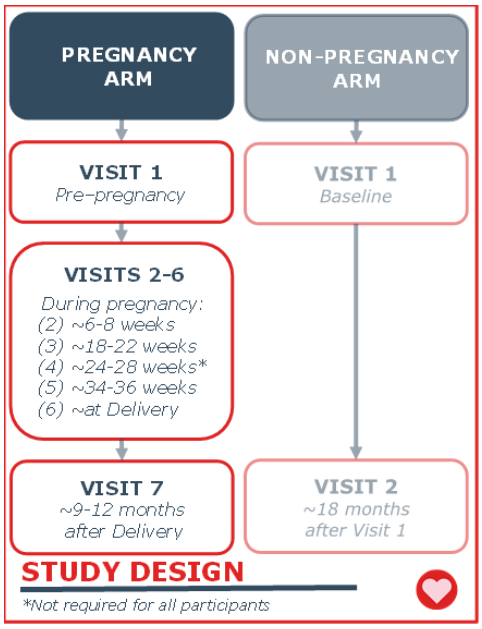
Preconception to pOst-partum study of cardiometabolic health in Primigravid PregnancY

Women who experience placental complications during pregnancy, such as high blood pressure, kidney problems or fetal growth restriction are at increased risk of developing heart disease and diabetes later in life. In this study, we are aiming to assess risk factors for heart disease and diabetes in women actively trying to conceive, before and during pregnancy. This is to see whether placental complications make a difference to heart health and how best to reduce these risk factors and potentially prevent placental syndromes in the future.

WHY HAVE I BEEN INVITED?

You are interested in being part of the POPPY study as you are planning a pregnancy in the next 12 months and you have contacted us in response to a recruitment poster or social media post about the POPPY study.

DO I HAVE TO TAKE PART?



It is entirely up to you to decide whether or not to take part. Participation is completely voluntary and we will respect your decision. If you decide to participate, you will be asked to sign an Informed Consent Form, but you are still free to change your mind and withdraw from the study at any time without giving a reason. If you choose not to participate or to withdraw from the study, your future medical treatment and normal standard of care will not be affected in any way.

WHAT'S INVOLVED?

You will be given the opportunity to talk with a member of the study team about what is involved and if you decide to participate, you will be asked to sign a consent form and we will inform your GP. You will attend up to 7 study visits, depending on whether you become pregnant within 12 months of your first visit, and if we ask you to attend additional visits for an Oral Glucose Tolerance Test and/or a visit

after the birth of your baby. At visits, the research team will carry out various assessments, which will mainly involve taking measurements and some blood/urine samples. You will not be asked to take any medication as part of this study.

WHAT IF I DECIDE I NO LONGER WISH TO PARTICIPATE IN THE STUDY?

You are free to withdraw from this study at any time without giving a reason and without affecting your future care or medical treatment. If you decide not to participate any further, no more tests will be performed. Any information already provided or results from tests already performed on you or your samples will continue to be used in the study. Any samples that you have already provided for the study can be destroyed at your request.

HOW WILL MY INFORMATION BE USED?

All information collected about you will be kept strictly confidential. Your personal and medical information will be kept in a secured file. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead. After the study, we will keep some of the data to check the results, and reports will be written in a way that no one can work out that you took part in the study.

De-identified information about your health and care may be made available for other research studies, to help maximize the benefits of conducting research and verify results. Before data are shared, all personal identifiers such as names, addresses and dates of birth, will be removed.

SCHEDULE OF ASSESSMENTS

PREGNANCY ARM	Informed Consent	Pregnancy test	Medical & Lifestyle History	Register with NHS England	Anthropometric measures	Blood pressure & arterial stiffness	Step test	Echocardiogram	Carotid IMT	Blood & Urine samples	Oral glucose tolerance test	Umbilical cord blood sample	Collect pregnancy data/outcomes
VISIT 1 Baseline	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
VISIT 2 ~6-8 weeks			✓		✓	✓		✓	✓	✓			✓
VISIT 3 ~18-22 weeks			✓		✓	✓		✓	✓	✓			✓
VISIT 4 ~24-28 weeks											✓*		
VISIT 5 ~34-36 weeks			✓		✓	✓		✓	✓	✓			✓
VISIT 6 ~at Delivery										✓†		✓‡	✓
VISIT 7 ~9-12 months after Delivery		✓	✓		✓	✓		✓	✓	✓			

*Test not required if completed as part of routine ante-natal care

†‡These samples are optional

Medical and lifestyle history will be completed and measurements, including height, weight, waist, hip ratio and body composition will be recorded. Echo/Carotid IMT will only be completed at sites where resources are available.

Further information about the assessments can be found in the full Participant Information Leaflet.

WHAT HAPPENS AFTER THE STUDY ENDS?

The results of the study will be published in scientific journals and presented at medical conferences after completion of the study. You will not be identified in any report or publication. As this is one of many ongoing studies at your local site, if you consent, we may contact you again in the future to see if you would be happy to take part in other ethically approved studies.

WHAT EXPENSES WILL I RECEIVE?

If you decide to participate in the study, we will pay you £35 per visit. We hope this will cover travel expenses and time associated with participating in the study. The payment can either be made after each visit or as a combined payment after all completed visits.

The POPPY study is jointly sponsored by Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge. Wellcome is funding the POPPY study.

Funded by Wellcome

THANK YOU

Thank you for taking the time to read about the POPPY study. Before you decide if you would like to be involved, please make sure you read the full participant information leaflet carefully, and talk about the study with your friends & family.

If you would like further information about the study, anything you have read is unclear or you have any unanswered questions, the study organisers can be contacted using the details below, and will be happy to discuss the study with you.

CONTACT US

Please refer to the "Take part" section on this website to identify the right contact person for your location.