

Confidentiality

All information will be held in the strictest confidence and the privacy of you and your baby will be upheld by the study team. None of your personal information will be shared with a third party. A study number will be assigned to each participant and data produced from this study will be stored in a secure, locked location. Only members of the research team will have access to the data. Following completion of the research study the data will be kept for 5 years and will subsequently be destroyed in compliance with data protection guidelines.

The study team may require access to your medical records and those of your baby. Again, any information collected will be completely de-identified.

Participation in this study will not in any way affect the care you receive during your pregnancy.

If you are interested in taking part in this study, please speak to one of the nurses/doctors at your booking visit.

HANDLE Study Information Booklet

Contract Details:

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HANDLE Study Information Booklet

The purpose of this study is to investigate if a non-invasive cardiac output monitor (NICOM) can identify early heart and blood vessel changes that eventually lead to pre-eclampsia.

Preeclampsia, a combination of high blood pressure and protein in the urine, is a condition that affects about 5 percent of pregnant women.

It can develop any time in the second half of pregnancy, including during labor or even after delivery.

Study Criteria:

1. Booking visit today
2. Expecting your first baby
3. Not expecting twins
4. No medical history of serious illness
5. Blood pressure < 140/90

Title of Study:

The HANDLE Study: Haemodynamic Assessment in pregnancy anD neonatal Echocardiography. A study identifying Abnormal Haemodynamic Profiles in Pregnancy as a Predictor of Adverse Obstetric Outcome and Characterisation of Neonatal Myocardial Performance in Infants.

Investigators:

Co-Principal Investigator: Prof Fergal Malone & Dr Afif EL-Khuffash

Co-Investigators: Dr Etaoin Kent, Dr Niamh Hayes

Purpose of the Research Study

Preeclampsia, a combination of high blood pressure and protein in the urine, is a condition that affects about 5 percent of pregnant women. It can develop any time in the second half of pregnancy, including during labor or even after delivery. At present there are no accurate ways to predict what women may be at risk of developing preeclampsia. Pregnant women at risk of developing preeclampsia may have changes in the way the heart and blood vessels work early on in pregnancy before any symptoms become apparent. The technology to reliably monitor these changes in a simple and painless manner has not been available until now. We plan to assess whether a non-invasive cardiac output monitor (NICOM) can identify early heart and blood vessel changes that eventually lead to pre-eclampsia.

We would also like to compare how NICOM measures the function of the heart with echocardiography (ultrasound of the heart).

Following the birth of your baby, we would like to assess the function of your baby's heart (during the first two days of life) by also using echocardiography to evaluate any possible effects of preeclampsia.

What does participation involve?

Participation in the study will involve an extra test being performed at 3 of your antenatal visits (at initial booking visit, 20 – 22 and 28 – 30 weeks) and also at 6 weeks following delivery of your baby. This test is a simple measure of your heart rate and blood pressure using a non-invasive cardiac monitor (NICOM). This is a completely painless procedure and carries **no risk to you or your baby.**

In addition a small number of study participants will be selected to undergo an echocardiogram. This is a painless ultrasound examination that looks at the function of your heart. The echocardiogram is risk-free and will take approximately 10 minutes. Those that are to have this test performed will be chosen at random. Following delivery a group babies in the study will be invited to have an echocardiogram lasting 10 minutes on the first and second days of life.

Participation in this study will not in any way affect the care you receive during your pregnancy.

Potential harms/risks

We do not anticipate any harms or discomforts for you or your baby as a result of participating in this study. The NICOM monitor requires only sticker electrodes to be applied to your skin, and can be disconnected from the machine easily. No adverse effects are expected as a result of this. NICOM has been tested and safely used without harm in adults, children, and pregnant women.

Echocardiograms on both mothers and babies are regularly performed as part of routine clinical care and are well-tolerated and safe. Participation in the study will involve extra echocardiogram examinations for your baby. If we find anything unusual or unexpected at the time of the echocardiogram in either you or your baby we will immediately inform you of the findings and we will notify the cardiology team in the hospital and seek their advice.

Potential Benefits

The information gained may provide insight into cardiovascular abnormalities that occur in pregnancy. We hope that this will help to inform our management of pregnancies in the future.

There may be no direct benefit to you now, but the results of this study will benefit future patients at high risk of pregnancy-induced high blood pressure or impaired fetal growth.

The benefit to your baby would be the chance finding of an undiagnosed heart or blood vessel condition. In such cases we would arrange for suitable follow-up and medical care.