

**Patient Information Leaflet**

***Study Title:***

**STOP** trial: **S**moking cessation **T**hrough **O**ptimisation of clinical care in **P**regnancy.

A randomised controlled trial of a smoking cessation antenatal clinic to optimise clinical care in pregnancy. This study aims to investigate the use of a specialist antenatal clinic for smokers in pregnancy.

***Invitation to take part***

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you fully understand what the research is about and what you will be asked to do. It is important that you read the following information in order to make an informed decision and if you have any questions about any aspects of the study that are not clear to you, do not hesitate to ask me. Please make sure that you are satisfied before you decide to take part or not. Thank you for your time and consideration of this invitation.

***Purpose of the Research Study***

This study will determine if the use of a dedicated smoking cessation antenatal clinic (the **STOP** clinic) results in higher rates of smoking cessation among pregnant women. We will measure various clinical outcomes for both mother and baby to see if the use of a dedicated clinic improves these outcomes. As part of this study, we will scan pregnant smokers at two extra timepoints in their pregnancy to assess their baby’s growth and wellbeing. Additionally, we will perform a blood test in a small subset of mothers to look at changes in platelets compared to non-smokers. This will involve a blood test at three points in the pregnancy. A short questionnaire will be provided to assess behaviour and habits of smoking.

***Why have I been asked to take part in this study?***

You have been asked to participate in the study because you are pregnant and have given a history of smoking during the pregnancy.

***Do I have to take part in the study?***

Taking part in this research study is entirely up to you and if you do decide to take part you will be provided with an information leaflet to take with you. Additionally, you will be asked to sign a consent form. However, if you do not wish to take part and if you change your mind at any time (prior to publication), you can withdraw from the Research Study without giving a reason.

***What will happen during the study?***

Patients taking part in the study will be randomised to either attending the **STOP** clinic or to attending a normal antenatal clinic, which is the usual routine care offered by a doctor or midwife.

* **The STOP clinic:**

If you are selected to attend the **STOP** clinic, all your care in the pregnancy will take place in this clinic. You will have a normal schedule of visits to the clinic and will have the support of a smoking cessation nurse based in the clinic. Everyone attending the clinic will have a smoking cessation intervention performed. This means planning a ‘Quit’ date with the support of a smoking cessation nurse, and having follow up visits in the clinic to check your progress. While we are encouraging all our patients to quit, we understand this is a difficult thing to do – you will remain in the clinic with full antenatal care whether you succeed in quitting or not.

* **Routine care:**

You will attend your normal antenatal clinic with your doctor or midwife.

***What extra tests will I have during the study?***

If you attend the STOP clinic you will have two extra scans at 32 and 36 weeks in addition to your normal schedule of scans at 12 and 20-22 weeks. These scans will monitor your baby’s growth and wellbeing. At each visit to the antenatal clinic, we will check your carbon monoxide levels by a breath test and we will measure cotinine levels in your urine via a urine sample. These are both markers of smoking.

A small group of mothers will have a blood sample taken at three timepoints in the pregnancy to assess their platelet biomarkers. Platelets are small cells in the blood which help your blood to clot.

***Are there any potential harms/risks?***

There are no potential harms or risks involved in participating in the study.

***Are there any potential benefits/lack of benefit?***

Yes. If you attend the **STOP** clinic, you will receive extra scans in your pregnancy. Additionally, you will be helped to quit smoking - which is of enormous benefit to both you and your baby.

***Confidentiality***

All information and results involved in the study are anonymised (cannot be traced back to your name) and stored on a secure computer in the research department that is only accessible by the researcher (which is password protected and encrypted).

**Contact details**

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**Consent Form**

**STOP** trial: **S**moking cessation **T**hrough **O**ptimisation of clinical care in **P**regnancy

A randomised controlled trial of a smoking cessation antenatal clinic with investigation of ultrasound and platelet parameters in smoking and non-smoking pregnant women.

**Patient Name:**

**Patient Number:**

I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I understand that sections of any medical notes may be looked at by the researcher where it is relevant to my taking part in this clinical investigation. I give permission for these individuals to have access to my records.

I consent to banking (storage) of my blood for subsequent analysis. These samples will be anonymous (i.e. nobody will know who you are). I understand that research (including genetic research), may be carried out on these samples by researchers working in the Coombe Women and Infants University Hospital in the future. I have been advised that any research conducted on these samples will have the prior ethical approval of the Research Ethics Committee of the Coombe Women and Infants University Hospital.

I agree to take part in the above study.

Patient Signature: ……………………………………….

Name in Capitals: ……………………………………….

Date: ……………………………………….

Researcher Signature: ……………………………………….

Name in Capitals: ……………………………………….

Date: ………………………………………. .

(Copy for researcher, copy for patient)