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Can a specialised antenatal clinic help pregnant women quit smoking and reduce the risk of complications for mother and baby?

Submission date
29/01/2018

Recruitment status
No longer recruiting

Registration date
08/02/2018

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Smoking during pregnancy results in poor outcomes for both mother and baby, in addition to many long-term consequences for the child. Smoking is associated with miscarriage, stillbirth, growth restriction in the womb, preterm birth and problems with the placenta during pregnancy. It is known that smoking is one of the biggest preventable risk factors for illness in a mother and baby. Importantly, stopping smoking while pregnant improves outcomes for both mother and baby. In the Coombe Hospital, over 1 in 10 women are smoking during their pregnancy. Babies of pregnant smokers suffer from growth restriction while in the womb, with this effect particularly seen in the later stages of pregnancy. Stopping smoking can prevent this. The aim of this study is to investigate the use of a dedicated 'quit smoking' antenatal clinic in pregnancy on quitting smoking rates, growth of the baby, and on mother and baby outcomes.

Who can participate?
Healthy pregnant women aged 18 and older who smoke.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group attend a specialised clinic (the STOP clinic) where all their care is managed by a 'quit smoking' team of obstetricians, midwives and experts in stopping smoking. At each visit participants are asked about their current smoking habits and have their current carbon monoxide levels measured by a simple breath test. Participants also receive ultrasound scans to measure blood flow and growth in the placenta and baby, and receive two extra scans at 32 and 36 weeks. Those in the second group have normal care in the Coombe with an obstetrician or midwife. This group is split into two further groups. Those in the first group have the two extra scans at 32 and 36 weeks, and the second group has no extra scans.

What are the possible benefits and risks of participating?
Participants may benefit from potentially quitting smoking which is of enormous benefit to both them and their baby. Additionally, they may receive extra scans in their pregnancy. There are no risks to participating in the study.

Where is the study run from?
Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
August 2017 to January 2020

Who is funding the study?
Coombe Women and Infants University Hospital and ‘Friends of the Coombe’ (Ireland)

Who is the main contact?
Dr Brendan McDonnell (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Brendan McDonnell

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STOPtrial

Study information

Scientific Title
Smoking cessation Through Optimisation of clinical care in Pregnancy - the STOP trial

Acronym
STOP

Study objectives

The aim of the study is to assess whether a novel smoking cessation antenatal clinic tailored to assist smoking cessation, incorporating a smoking cessation practitioner leads to better maternal and neonatal outcomes in pregnancy, and whether it helps more women to achieve cessation during pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coombe Women and Infants University Hospital Research and Ethics Committee, 10/01/2018, ref: Study 25-2017

Study design
Single-centre pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Smoking in pregnancy

Interventions
Current intervention as of 06/12/2018:
Women who smoke in pregnancy are randomised at first visit to either the STOP clinic or 'routine care'.

In the STOP clinic, they have consultant-led antenatal care with the addition of a dedicated smoking cessation practitioner who is in-built into the clinic. As smokers are at risk of late-onset intrauterine growth restriction (IUGR) they are scanned at 32 and 36 weeks gestation. 225 women are assigned to the intervention arm and 226 to 'routine care' - 113 of the routine care group receive the additional scans at 32 and 36 weeks, and 113 who do not receive any additional scans.

Smoking status is biologically quantified and measured at each visit. They receive smoking cessation reviews at booking visit, 1 week post quit date, 4 weeks, 3 months and 6 months or end of pregnancy. A final cessation status is recorded in the postnatal period.

Previous intervention:
Women who smoke in pregnancy are randomised at first visit to either the STOP clinic or a pre-defined 'routine care'.

In the STOP clinic, they have consultant led antenatal care with the addition of a dedicated smoking cessation practitioner who is in-built into the clinic. As smokers are at risk of late-onset intrauterine growth restriction (IUGR) they are scanned at 32 and 36 weeks gestation. 300 women are assigned to the intervention arm and 300 to pre-defined 'routine care' - 150 of the routine care group receive the additional scans at 32 and 36 weeks, and 150 who do not receive any additional scans.

Smoking status is biologically quantified and measured at each visit. They receive smoking cessation reviews at booking visit, one week post quit date, 4 weeks, three months and six months/end of pregnancy. A final cessation status is recorded in the postnatal period.

Intervention Type
Behavioural

Primary outcome measure
Self-reported continuous abstinence from smoking between the quit date and end of pregnancy (quit date is targeted as being at or before 16 weeks gestation and no further than 28 weeks gestation). This is validated using the exhaled carbon monoxide (CO) or urinary cotinine measured at one week, four weeks, three months and six months post quit date.

Secondary outcome measures
1. Reduced cigarette intake at 3 months post quit date, 6 months post quit date, end of pregnancy and at 6 months postpartum, validated using the exhaled carbon monoxide (CO) or urinary cotinine
2. Urge to smoke, measured using behavioural questionnaire at the end of pregnancy and 6 months after the birth
3. Tobacco withdrawal symptoms, measured using behavioural questionnaire at end of pregnancy and 6 months after the birth
4. Self- confidence in stopping smoking, measured using behavioural questionnaire at end of pregnancy and 6 months after the birth
5. Self-reported depression, measured using questionnaire at end of pregnancy and 6 months after the birth
6. Fetal morbidity and mortality outcomes are prospectively collected:
6.1. Miscarriage
6.2. Stillbirth
6.3. Neonatal death
6.4. Birth weight
6.5. Estimated fetal weight at 32 weeks
6.6. Estimated fetal weight at 36 weeks
6.7. Spontaneous pre-term birth
6.8. Iatrogenic pre-term birth
6.9. Birth injury
6.10. Neonatal complication
6.11. Oxygen dependence
6.12. Admission to neonatal unit
6.13. Length of stay of neonate
7. Maternal morbidity and mortality outcomes are prospectively collected:

7.1. Maternal death
7.2. Mode of delivery
7.3. Need for induction/delivery
7.4. Maternal need for intensive care
7.5. Maternal length of stay
7.6. Pre-eclampsia
7.7. Pregnancy induced hypertension
7.8. Postpartum haemorrhage
7.9. Blood transfusion
7.10. Late maternal complication
8. Satisfaction with results of care, measured using questionnaire in postnatal period
9. Confidence as an active participant in health care decisions, measured using questionnaire in postnatal period
10. Confidence in healthcare providers, measured using questionnaire in postnatal period
11. Birth experience, measured using questionnaire in postnatal period

Overall study start date
01/08/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. ≥ 18yrs old
2. Singleton pregnancy
3. Smoking ≥ 1 cigarette daily
4. English language spoken

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
450

Total final enrolment
434

Key exclusion criteria

1. Significant maternal medical disorder, eg. cardiac, haematological or endocrine disease (including GDM on metformin or insulin) requiring specialised maternal antenatal care.
2. Significant maternal psychiatric disorder, eg. delusional or psychotic disorders, severe depression requiring hospitalisation, use of ≥2 psychotropic drugs for treatment.
3. Serious co-morbid addiction issues eg opiate abuse, methadone maintenance program
4. Positive serology requiring specialised antenatal care
5. Significant fetal anomaly defined as aneuploidy, life limiting or lethal fetal anomaly
6. Intellectual disability or lack of capacity
7. Poor English / No English

Date of first enrolment
12/02/2018

Date of final enrolment
11/03/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infants University Hospital
Cork Street
Dublin 8
Ireland
D08 XW7X

Sponsor information

Organisation
Royal College of Surgeons in Ireland

Sponsor details
123 St Stephen's Green
Dublin
Ireland
D02 YN77

Sponsor type
University/education

Website
www.rcsi.ie

ROR
https://ror.org/01hxy9878

Organisation
Coombe Women and Infants University Hospital

Sponsor details
Cork Street
Dublin
Ireland
D08 XW7X

Sponsor type
Hospital/treatment centre

Website
www.coombe.ie

Funder(s)

Funder type
Charity

Funder Name
Friends of the Coombe

Results and Publications

Publication and dissemination plan
This project will be written up as a publicly available thesis in RCSI. Academic research papers will be written and published in peer reviewed journals by the research team. The outcomes of our research will be presented at national obstetric and public health forums. Additionally, the research team plan to present their work widely at both national and international conferences. Plans to publish the trial protocol in full later this year in a peer reviewed journal.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Brendan McDonnell bmcdonnell@rcsi.ie

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		06/12/2018	06/12/2018	No	Yes
Protocol article	protocol	03/09/2019		Yes	No
Results article		07/10/2022	27/10/2022	Yes	No