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Double-blind, randomised, placebo-controlled trial of nicotine replacement therapy in pregnancy

Submission date
03/05/2005

Recruitment status
No longer recruiting

Registration date
21/06/2005

Overall study status
Completed

Last Edited
12/05/2016

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
Women are highly motivated to stop smoking in pregnancy. Nicotine replacement therapy (NRT) is a medically-approved way to take nicotine by means other than tobacco, to help the patient stop smoking. The aim of this study is to assess the effectiveness and cost effectiveness of nicotine replacement therapy during pregnancy, and to find out whether it has any effect on children's behaviour and cognitive development at two years of age.

Who can participate?
Women who are between 12 and 24 weeks pregnant and who smoke at least five cigarettes daily

What does the study involve?
Participants are randomly allocated to receive an eight-week course of NRT patches or placebo (dummy) patches. Participants also receive individual behavioural support. Four weeks after their quit dates, women who are not smoking are issued with a second four-week supply of patches.

What are the possible benefits and risks of participating?
If NRT is demonstrated to be effective and safe in pregnancy, more pregnant smokers will use NRT whilst they are pregnant. This will increase the number of women who successfully stop smoking during pregnancy and will improve women's health. Reducing smoking during pregnancy will, in turn, lower the incidence of miscarriage, stillbirth and low birth weight. Smoking in pregnancy is also associated with childhood illness including an increased risk of asthma, sudden infant death syndrome and learning problems, so reducing smoking is likely to decrease the frequency of these problems. Finally, it is recognised that teenagers are more likely to initiate smoking if their parents smoke. Consequently, reducing smoking in pregnancy is likely to cause longer term reductions in smoking by young people.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
February 2006 to November 2012

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Sue Cooper
sue.cooper@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Sue Cooper

Contact details
SNAP Trial Office
University of Nottingham
Academic Division of Obstetrics & Gynaecology
City Hospital Maternity Unit
Hucknall Road
Nottingham
United Kingdom
NG5 1PB
+44 (0)115 823 1898
sue.cooper@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/07/01

Study information

Scientific Title
Double-blind, randomised, placebo-controlled trial of nicotine replacement therapy in pregnancy (SNAP)

Acronym
SNAP

Study objectives
1. To compare at delivery: the effectiveness and cost effectiveness for achieving biochemically-validated smoking cessation of nicotine replacement therapy and placebo patches in pregnancy
2. To compare at two years after delivery: the effects of maternal nicotine replacement therapy and placebo patch use in pregnancy on behaviour and cognitive development in children

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/060701
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51290/PRO-06-07-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxfordshire REC A ethics committee, ID number 04/Q1604/85

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pregnancy/Childbirth

Interventions
Treatment group:
Pregnant women will receive an eight week course of 15 mg/16 hour NRT transdermal patches. Although many studies have used longer courses, there is no evidence that these are more effective. Patches will be issued in conjunction with individual behavioural support which is an effective smoking cessation intervention in pregnancy. Four weeks after their quit dates, women who are not smoking will be issued with a second four week supply of patches.

Control group:
Women in the control arm of the trial will receive an identical placebo NRT patch and the same behavioural support as those in the treatment group.

In both control and intervention groups, participants will be blind to their group allocation.

Intervention Type
Other

Primary outcome measure
Self-reported, prolonged and total abstinence from smoking or the use of any non-pharmacological nicotine containing substances between a quit date set within two weeks of randomisation and immediately prior to childbirth.

Prolonged abstinence cannot be comprehensively validated, but if participants report prolonged abstinence and are abstinent at both time points below, they will be considered to have a positive primary outcome:
1. Self reported smoking cessation for at least 24 hours before follow-up at one month after quit date, validated by exhaled Carbon Monoxide measurement
2. Self reported smoking cessation for at least 24 hours before hospital admission for childbirth, validated by exhaled Carbon Monoxide or salivary cotinine measurement

Secondary outcome measures
1. Smoking:
1.1. Self reported, prolonged abstinence from smoking between quit date and one month
1.2. Self reported, prolonged abstinence from smoking between quit date and 6 months after delivery
1.3. Self reported smoking cessation for previous 7 day period at 6 months after delivery (point prevalence)
1.4. Self reported, prolonged abstinence from smoking between quit date and 2 years after delivery
1.5. Self reported smoking cessation for previous 7 day period at 2 years after delivery (point prevalence)
2. Foetal loss and morbidity:
2.1. Foetal death and stillbirth
2.2. Neonatal death (i.e. from birth to 28 days)
2.3. Post-neonatal death (29 days to 2 years)
2.4. Individualised birth weight Z score (i.e. birth weight adjust for gestational age, maternal height, maternal weight at booking and ethnic group)
2.5. Apgar score
2.6. Cord blood pH
2.7. Gestational age at birth
2.8. Intraventricular haemorrhage
2.9. Neonatal enterocolitis
2.10. Neonatal convulsions
2.11. Congenital abnormality
3. Maternal morbidity and mortality:
3.1. Maternal mortality
3.2. Mode of delivery
3.3. Proteinuria
3.4. Hypertension in pregnancy
4. Early childhood outcomes:
4.1. Behaviour and development at 2 years
4.2. Disability at 2 years
4.3. Respiratory symptoms at 2 years
5. Health economic data:
5.1. Duration of maternal hospital admission for childbirth

5.2. Duration of any admission (of baby) to special care
5.3. Health status at 6 months (EQ5D)

Overall study start date
01/02/2006

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Eligible women are women between 12 and 24 weeks pregnant
2. Report smoking at least ten cigarettes daily before pregnancy
3. Still currently smoke at least five cigarettes daily
4. An exhaled Carbon Monoxide (CO) reading above 8 ppm

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
1050

Key exclusion criteria
Women with the following contraindications to the use of NRT will be excluded:
1. Severe cardiovascular disease
2. Unstable angina
3. Cardiac arrhythmias
4. Recent cerebrovascular accident or Transient Ischaemic Attack (TIA)
5. Chronic generalised skin disorders or known sensitivity to nicotine patches
6. Chemical dependence/alcohol addiction problems
7. Women who cannot give informed consent and those with known major foetal anomalies will also be excluded

Intra-Uterine Growth Restriction (IUGR) is not an exclusion criterion.

Date of first enrolment
01/02/2006

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

Website
http://nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/01/2007		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/06/2014		Yes	No
Results article	results	01/08/2014		Yes	No
Results article	follow-up results	01/09/2014		Yes	No