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Helping pregnant smokers quit: a multi-centre study of electronic cigarettes and nicotine patches

Submission date
20/03/2017

Recruitment status
No longer recruiting

Registration date
21/03/2017

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Smoking in pregnancy remains an unresolved issue. Quit rates in pregnant smokers are low and advice by doctors and nurses, even when combined with behavioural support and nicotine replacement treatment (NRT), has only a limited effect. NRT (e.g. nicotine patch) has shown little effect most likely because pregnant women use them very little. Pregnant women also use up nicotine faster, and standard NRT doses may be too slow and too low for them. Nicotine patches also do not allow the dose to be tailored to smokers' needs. Electronic cigarettes (EC) may overcome these limitations. ECs allow flexible dosing and have a faster effect than NRT. They also provide some of the sensations and enjoyment that smokers get from smoking. These characteristics should ensure better treatment uptake. It is estimated that in the UK half a million smokers have switched from smoking to vaping (EC use) so far, with some 20,000 quitting smoking with the help of EC per year who would not have quit otherwise. The EC must therefore be tested as a stop-smoking treatment for pregnant women, but the safety of such treatment needs to be addressed. ECs do not contain most of the chemicals responsible for health risks of smoking and those that are present are there at levels much lower than those present in cigarette smoke. The overall risks of EC use are estimated to be 95% less than risks of smoking. No chemicals other than nicotine have been identified in EC vapour that would be expected to affect the health of the baby. NRT is universally used by the UK pregnancy stop smoking services because pregnant smokers are consuming nicotine anyway and because the harm to the baby is also caused by other chemicals in tobacco smoke which are absent in NRT. The same logic applies to nicotine intake from ECs. The safety concerns are reduced by the fact that ECs would be used as a replacement for cigarettes which pose well known dangers. If there is any sign of an increased risk, the study can be stopped. If such use involves risks, evidence of this would have important practical implications. The aim of this study is to find out whether ECs are more effective at helping pregnant women to quit smoking than NRT.

Who can participate?
Women aged 18 or over, who are 12 to 24 weeks pregnant, smoke daily and want help with stopping smoking

What does the study involve?
Participants are randomly allocated to use either an EC or nicotine patches. The products are posted out to participants, and they are called by a stop smoking advisor shortly after to check they know how to use the product and to set a quit day. The advisor then calls the participant weekly for a further 5 weeks to provide support and check on their progress. Participants are followed up at the end of their pregnancy and also at 3 months after birth. Smoking quit rates and side effects from the two treatments are compared at end of pregnancy and at 3 months after birth.

What are the possible benefits and risks of participating?
The benefit to participants is that taking part may help them to stop smoking, improving not only their health, but also the health and wellbeing of their baby. A positive result would also provide a new, inexpensive, and practical way to tackle an important and so far unresolved problem. No risks to participants are expected. Nicotine patches are approved to be used in pregnancy, and ECs do not pose any risks greater than cigarettes, which participants are already smoking.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
May 2017 to November 2020 (updated 14/04/2021, previously: April 2021)

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

Who is the main contact?
Dr Dunja Przulj

Contact information

Type(s)
Scientific

Contact name
Dr Dunja Przulj

Contact details
Health and Lifestyle Research Unit
Queen Mary University of London
2 Stayner's Road
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Additional identifiers

EudraCT/CTIS number
2017-001237-65

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
011822; HTA 15/57/85

Study information

Scientific Title
Helping pregnant smokers quit: a multi-centre RCT of electronic cigarette and nicotine patches

Acronym
PREP

Study objectives
Smoking in pregnancy remains an unresolved issue. Quit rates in pregnant smokers are low and advice by doctors and nurses, even when combined with behavioural support and nicotine replacement treatment (NRT) has only limited efficacy. NRT has shown little effect most likely because pregnant women use them very little. Pregnant women also metabolise nicotine faster and standard NRT doses may be too slow and too low for them. Nicotine patches also do not allow dosing tailored to smokers' needs.

Electronic cigarettes (EC) may overcome these limitations. EC allow flexible dosing and have a faster effect than NRT. They also provide some of the sensations and enjoyment that smokers get from smoking. These characteristics should ensure better treatment adherence.

The trialists hypothesise that EC may be more effective in helping pregnant women to quit smoking than NRT.

More details can be found at: https://www.journalslibrary.nihr.ac.uk/programmes/hta/155785/#/

Ethics approval required
Old ethics approval format

Ethics approval(s)
London- South East Research Ethics Committee, 29/06/2017, REC ref: 17/LO/0962

Study design
Multi-centre open-label randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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 cessation

Interventions
Randomisation will be conducted by a web-based application system created by the trialists' clinical trials unit. Randomisation will be in blocks of mixed sizes. Allocation is 1:1.

Participants will be randomised (1:1) to receive either nicotine patches for up to 8 weeks (15mg /16hr) or an e-cigarette starter pack. Both groups will receive weekly telephone support for 6 weeks from specialist stop smoking advisors. Participants will be follow up at the end of pregnancy and at 3 months postpartum.

Intervention Type
Mixed

Primary outcome measure
Prolonged abstinence rates at the end of pregnancy, defined as per Russell Standard (up to 5 lapses allowed from 2 weeks after the target quit day until end of pregnancy, with no smoking at all during the previous week at the time of follow-up), and verified by salivary cotinine (< 15 ng /ml) for those not reporting using any nicotine product and anabasine (< 1 ng/ml) for those reporting other forms of nicotine use.

Secondary outcome measures
1. Smoke intake and nicotine intake, measured by salivary anabasine and salivary cotinine levels, assessed for participants still using NRT or EC at end of pregnancy and for ‘dual users’
2. 7-day point-prevalence abstinence (not a puff in the last 7 days), self-reported at 4 weeks, end of pregnancy and at 3 months post-partum
3. Prolonged abstinence, self-reported at end of pregnancy and 3 months post-partum
4. Use of NRT and EC throughout pregnancy, measured by asking participants on how many days they used their products at each weekly contact and at follow-ups
5. Safety examined by looking at the proportion of participants reporting adverse events and serious adverse events in each group throughout pregnancy; proportion of participants in each group reporting adverse events and serious adverse events for themselves or their infant at 3 months post-partum; and differences in birth and maternal outcomes between the two groups

Overall study start date
01/05/2017

Completion date
26/11/2020

Eligibility

Key inclusion criteria
1. Daily smokers
2. 12 to 24 weeks pregnant
3. Wants help with stopping smoking
4. Willing to be randomised to use either NRT or EC (to avoid selective drop-out and contamination)
5. Wiling to receive 6 weekly support calls over the phone plus two follow-up calls
6. Speaks English (to allow data collection via phone)
7. Aged 18 years or over

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
1,142

Total final enrolment
1140

Key exclusion criteria
1. Known allergic reaction to nicotine skin patches (a contraindication for patch use)
2. Current daily use of NRT or EC
3. Taking part in another interventional trial
4. Serious medical problem or high-risk pregnancy (to avoid problems with follow-up and data collection)

Date of first enrolment
01/01/2018

Date of final enrolment
07/11/2019

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Queen Mary University of London
United Kingdom
E1 4AH

Study participating centre
Countess of Chester Hospital
Chester
United Kingdom
CH2 1UL

Study participating centre
Royal Preston Hospital
Preston
United Kingdom
PR2 9HT

Study participating centre
Leighton Hospital
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Warrington & Halton Hospital
Warrington
United Kingdom
WA5 1QG

Study participating centre
Queen Elizabeth Hospital Gateshead
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Royal Victoria Infirmary
Newcastle upon Tyne

United Kingdom
NE1 4LP

Study participating centre
Sunderland Royal Hospital
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Cumberland Infirmary
Carlisle
United Kingdom
CA2 7HY

Study participating centre
Bradford Royal Hospital
Bradford
United Kingdom
BD9 6RJ

Study participating centre
St Mary's Hospital, Manchester
Manchester
United Kingdom
M13 9WL

Study participating centre
Burnley General
Burnley
United Kingdom
BB10 2PQ

Study participating centre
North Manchester General/ Royal Oldham
Manchester
United Kingdom
M8 5RB

Study participating centre
Birmingham Womens Hospital
Birmingham
United Kingdom
B15 2TG

Study participating centre
Royal Stoke Hospital
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Birmingham City Hospital
Birmingham
United Kingdom
B18 7QH

Study participating centre
Princess Royal Hospital, Telford
Telford
United Kingdom
TF1 6TF

Study participating centre
Royal Devon & Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Study participating centre
Derriford Hospital, Plymouth
Plymouth
United Kingdom
PL6 8DH

Study participating centre

NHS Forth Valley
Stirling
United Kingdom
FK9 4SW

Study participating centre
Nottingham University Hospitals
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Russels Hall, Dudley
Dudley
United Kingdom
DY1 2HQ

Study participating centre
University Hospitals of Derby & Burton
Derby
United Kingdom
DE22 3NE

Study participating centre
Heart of England NHS
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
Joint Research Management Office
QM Innovation Building
5 Walden Street
London

England
United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

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
The results of the study will be published in a high-impact peer reviewed journal.

Intention to publish date
01/05/2022

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 Dunja Przulj.

Added 12/09/2017:
Once the study is published, if a researcher/academic requests the dataset or part of the dataset (for example if conducting a review/meta-analysis), then they will be provided with the Excel

data file if necessary. Data is archived electronically for 20 years. Any data shared will be completely anonymised, and as consent has not been requested from participants for this.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/05/2022	17/05/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/07/2023	16/10/2023	Yes	No
Other publications	A qualitative study of factors influencing adherence	07/01/2021	17/06/2025	Yes	No