

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

Submission date 20/03/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 21/03/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/06/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
London
United Kingdom
E1 4AH

Additional identifiers

Clinical Trials Information System (CTIS)

2017-001237-65

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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 followed up at the end of pregnancy and at 3 months postpartum.

Intervention Type

Mixed

Primary outcome(s)

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.

Key secondary outcome(s)

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

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. Willing 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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**

United Kingdom

England

Scotland

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

ROR

<https://ror.org/026zzn846>

Funder(s)**Funder type**

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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
Results article		01/07/2023	16/10/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	A qualitative study of factors influencing adherence	07/01/2021	17/06/2025	Yes	No