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Electronic cigarettes: Nicotine delivery in users

Submission date
18/06/2014

Recruitment status
No longer recruiting

Registration date
26/06/2014

Overall study status
Completed

Last Edited
14/11/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Electronic cigarettes (ECs) are a developing technology that aims to provide nicotine without the harmful chemicals produced by smoking tobacco. ECs have the potential to be of substantial public health benefit if there is a switch from smoking to EC use on a wide scale. However, only some 12%- 14% of smokers who have tried EC models then go on to use them on a daily basis. This suggests that the current generation of EC products does not yet quite provide what smokers get from smoking real cigarettes. The way in which the nicotine is delivered is likely to play a major role. ECs are vaporizers; they heat up a nicotine-containing liquid which then turns into vapour that is inhaled. Our previous work has shown that different EC brands differ widely in how much nicotine they release into the vapour (i.e. nicotine delivery). Some ECs will provide more nicotine and at a faster rate than others, a fact that is likely to appeal to many smokers. Other EC characteristics such as taste, how easy it is to use, the amount of vapour produced, how it feels in the hand and cost are likely to be play a part too, but it can be expected that nicotine delivery will be the most important consideration. One sign of this is that nicotine containing ECs dominate the market, with nicotine free models are hardly used despite being otherwise equivalent and widely available. As EC technology develops there is a need to monitor pharmacokinetic (PK) characteristics of different EC brands (i.e. how the chemicals used in different ECs are handled in the human body). Such data are needed to guide the choice of EC brands for studies of the potential of ECs in stopping people from smoking , to estimate the market potential of different brands, and to guide further product development. This is a proposal to collect such data from a range of ECs to compare their nicotine delivery with each other and with nicotine delivery from a conventional cigarette. The aim of the study is to assess PK profiles of a range of ECs (at least 4 and up to 15 different EC brands) and to compare these brands and conventional cigarettes.

Who can participate?
Adults aged 18 or over, who have used ECs daily for at least one month and still smoke conventional cigarettes at least occasionally.

What does the study involve?
Participants attend each of the sessions after not smoking wither conventional cigarettes or ECs overnight. Each session is arranged so that there is at least 3-day wash out period (break) between them. They take place between 7.30 and 9.30 am, depending on the participants availability, and take about 90 minutes. At the first session, participants are asked to smoke a

cigarette of their usual brand which they have been asked to bring along. At all further sessions, participants are given a EC (a different brand at each session). At each session, participants report on their overnight smoking/EC use and provide expired air carbon monoxide (CO) readings. A baseline blood sample is taken, after which participants will be asked to smoke/use EC ad-lib for 5 minutes. Further blood samples will be taken at 2, 4, 6, 8, 10, and 30 minutes after starting smoking/EC use. Three to five millilitres of blood are collected at each of these time points. Number of puffs are recorded. Urges to smoke are rated upon arrival, before smoking /using EC and then at 5, 10, 15 and 30 minutes. At the end of the session, participants rate each product for its sensory characteristics, satisfaction, etc.

What are the possible benefits and risks of participating?
The study is not expected to pose any risks as the volunteers will be smokers who are also regular EC users. However, any adverse effects will be carefully monitored. Blood sampling will be done with one venipuncture per session, performed by an experienced phlebotomist. Potential benefits are that current EC users will be able to try and test several different EC brands that they may not have otherwise tried, and they may find these brands satisfying and/or helpful in reducing their urges to smoke.

Where is the study run from?
The Tobacco Dependence Research Unit, Wolfson Institute of Preventive Medicine, Queen Mary, University of London (UK)

When is the study starting and how long is it expected to run for?
June 2014 to June 2017

Who is funding the study?
Exane Limited (UK)

Who is the main contact?
Anna Phillips
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2.0

Study information

Scientific Title
Electronic cigarettes - nicotine delivery in users: A crossover study

Study objectives
The objective of the study is to establish pharmacokinetic profiles of a range of electronic cigarettes (at least 4 and up to 15 different EC brands) and to compare the key parameters between the brands and with participants own cigarette.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast Surrey, 13/04/2014, ref. 14/LO/0358

Study design
Crossover study

Primary study design
Observational

Secondary study design
Single-centre

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Smoking Cessation

Interventions
This is a crossover study in which 7 adults who smoke at least occasionally and who are regular electronic cigarette (EC) users will test at least 4 (and up to 15) different brands of electronic cigarettes to determine their nicotine delivery profiles. Participants will attend sessions after overnight abstinence from both smoking and EC use. At the first session, participants will be

asked to smoke a cigarette of their usual brand which they will be asked to bring along. At all further sessions, participants will be provided with an EC (a different brand at each session). Each brand will be tested at a different session, and sessions will be scheduled with at least 3-day wash out periods between them. The sessions will take will take about 90 minutes. To determine the nicotine delivery profiles at each session a baseline blood sample will be taken, after which participants will be asked to smoke/use EC ad-lib for 5 minutes. Further blood samples will be taken at 2, 4, 6, 8, 10, and 30 minutes after starting smoking/EC use. Three to five millilitres of blood will be collected at each of these time points. Number of puffs will be recorded. Urges to smoke will be rated upon arrival, before smoking/using EC and then at 5, 10, 15 and 30 minutes. At the end of the session, participants will rate each product for its sensory characteristics, satisfaction, etc. There are no follow-up sessions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
PK characteristics of each EC brand.

Secondary outcome measures
1. Comparisons between each brand and conventional cigarette
2. Ranking of brands in Cmax (the highest drug concentration observed in plasma following EC use)
3. Tmax (time at which the highest nicotine concentration occurred in plasma following EC use)
4. AUC (estimated area under the plasma nicotine curve concentration)
5. User ratings

Overall study start date
25/06/2014

Completion date
25/06/2017

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Experienced EC users (using EC daily for at least one month) who still smoke conventional cigarettes at least occasionally
3. Willing to attend a series of morning sessions and provide blood samples

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
7

Key exclusion criteria
1. Pregnant or breastfeeding
2. Current serious illness
3. Enrolled in other research

Date of first enrolment
25/06/2014

Date of final enrolment
26/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Tobacco Dependence Research Unit
London
United Kingdom
E1 2JH

Sponsor information

Organisation
Queen Mary, University of London (UK)

Sponsor details
Queen Mary Innovation Centre
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Industry

Funder Name
Exane Limited (UK)

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?
Basic results		14/11/2018	14/11/2018	No	No
HRA research summary			28/06/2023	No	No