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Vascular effects of regular cigarettes versus electronIc cigarettes

Submission date
23/08/2016

Recruitment status
No longer recruiting

Registration date
27/09/2016

Overall study status
Completed

Last Edited
25/05/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Electronic cigarettes, also known as e-cigarettes or vaping, are being used by more and more people to help them stop smoking. There have been many claims in the media about the safety of e-cigarettes. E-cigarettes are sold on the principle that they are a much safer alternative to traditional cigarettes because they don't contain harmful substances like tobacco and tar. However, most e-cigarettes, like traditional cigarettes, do contain nicotine which may be harmful to blood vessels. The aim of this study is to compare the blood vessel health of people using e-cigarettes containing nicotine, people using e-cigarettes without nicotine, and people smoking tobacco cigarettes.

Who can participate?
People aged 18 and over who currently smoke

What does the study involve?
Participants are randomly allocated into one of three groups. The first group continues smoking tobacco cigarettes (the participants' own). The second group switches to smoking electronic cigarettes containing nicotine and flavour. The third group switches to smoking electronic cigarettes containing flavour alone. Participants' blood vessel health is assessed at the start of the study and after 28 days.

What are the possible benefits and risks of participating?
There may not be direct benefits to the participants except that all participants will be provided with smoking cessation advice and support at the end of the study. The procedure used to assess blood vessel health is called Flow Mediated Dilatation, which involves inflating a blood pressure cuff that may be uncomfortable. Patients are also required to provide blood samples to look for markers of blood vessel health.

Where is the study run from?
Ninewells Hospital and Medical School (UK)

When is the study starting and how long is it expected to run for?
August 2016 to November 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
1. Mrs Pippa Hopkinson
2. Dr Jacob George

Contact information

Type(s)
Public

Contact name
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02878421

Secondary identifying numbers

2014CV10

Study information

Scientific Title
Vascular EffectS of regUlar cigarettes Versus electronIc cigarette USe: a randomised controlled trial

Acronym
VESUVIUS

Study objectives
Endothelial function will be improved on electronIc cigarettes (EC) compared to tobacco cigarettes (TC) when measured by flow-mediated dilatation (FMD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of Scotland Research Ethics Service (EoSRES), 26/07/2016, REC ref: 16/ES/0087, Protocol number: 2014CV10, IRAS project ID: 207653

Study design
Single-centre three-cohort parallel-group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

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

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

Interventions
Randomisation will be carried out in a 1:1:1 fashion via a centrally controlled web-based GCP compliant randomisation system. To ensure balanced assignment across critical variables, a minimisation algorithm will be employed, using baseline age (≤40 years & >40 years) and smoking pack years (≤20 pack years & > 20 pack years).

1. Continue with tobacco cigarettes (participants' own)
2. Switch to electronic cigarettes containing 16mg nicotine plus flavour
3. Switch to electronic cigarettes containing flavour alone

Treatment period 28 days (+/- 10 days)

Endothelial function will be measured non-invasively at 0 and 4 weeks using the standard technique of flow mediated dilatation (FMD) of the brachial artery in response to hyperemia and to sublingual GTN. Brachial artery diameter and flow are determined by M mode and Doppler ultrasound.

Intervention Type
Other

Primary outcome measure
Difference in flow-mediated dilation (a measure of endothelial dysfunction) between the traditional cigarette group and the electronic cigarette-nicotine-free groups at 0 and 4 weeks

Secondary outcome measures
1. Difference in flow-mediated dilation (a measure of endothelial dysfunction) between electronic cigarette-16 mg nicotine and electronic cigarette-nicotine free groups at 0 and 4 weeks
2. Difference in Pulse Wave Velocity (a measure of arterial stiffness) between the traditional cigarette group and the electronic cigarette-nicotine free groups at 0 and 4 weeks
3. Difference in Augmentation Index@75bpm (a measure of arterial stiffness) between the traditional cigarette group and the electronic cigarette-nicotine free groups at 0 and 4 weeks

Overall study start date
01/08/2016

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Currently smoking ≥15 full strength tobacco cigarettes per day for at least 2 years, or roll-up tobacco equivalent (cigar or pipe smokers will not be included).
3. Willing to stop tobacco cigarettes for period of study if required
4. Willing not to use electronic cigarettes if required
5. Able to give informed consent

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
135

Total final enrolment
145

Key exclusion criteria
1. Pregnant or lactating
2. Women of childbearing potential who do not abstain from sex or use effective contraception
3. On current prescribed medication for cardiovascular disease
4. History of cardiovascular disease (excluding hypertension), diabetes, active malignance or chronic renal disease
5. Nut allergy
6. Participation in another clinical trial (other than observational trials and registries) with an investigational product and/or intervention within 30 days before visit 1

Date of first enrolment
01/09/2016

Date of final enrolment
30/06/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital and Medical School
Dundee
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Sponsor information

Organisation
University of Dundee

Sponsor details
Ninewells Hospital & Medical School
TASC R & D Office
Residency Block Level 3
George Pirie Way
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Sponsor type
University/education

Website
tasc-research.org

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/12/2019	25/05/2020	Yes	No
HRA research summary			28/06/2023	No	No