

Vascular effects of regular cigarettes versus electronic cigarettes

Submission date 23/08/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/09/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/05/2020	Condition category Other	☐ 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02878421

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

Scotland

Study participating centre

Ninewells Hospital and Medical School

Dundee

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Sponsor information

Organisation

University of Dundee

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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