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Nicotine absorption from electronic cigarettes

Submission date
12/02/2014

Recruitment status
No longer recruiting

Registration date
28/02/2014

Overall study status
Completed

Last Edited
21/01/2019

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 have been recently marketed as an alternative to smoking. Limited information is available about the nicotine pharmacokinetics (the action of nicotine in the body over a period of time) from using such devices. The purpose of this study is to evaluate nicotine absorption from electronic cigarette use and compare experienced users with naive users.

Who can participate?
Healthy smokers and healthy electronic cigarette users.

What does the study involve?
At the start of the study both experienced smokers and naive users will have to abstain from nicotine intake for at least 8 hours, then nicotine levels will be measured. Subsequently they will be given an electronic cigarette device with a nicotine liquid. They will use the device for 5 minutes taking 10 puffs and for 60 more minutes taking as many puffs as they like. Blood samples for nicotine measurements will be obtained at 5 min, 20 min, 35 min, 50 min and 65 min. The blood samples will be collected through a catheter that will be inserted into a vein.

What are the possible benefits and risks of participating?
There is minimal risk associated with obtaining blood samples through a venous catheter. An increase in anxiety may be experienced due to not smoking and not using electronic cigarettes for 8 hours. Nicotine craving symptoms may be expected, but will be relieved after the initial blood sample collection.

Where is the study run from?
Onassis Cardiac Surgery Center, Greece.

When is the study starting and how long is it expected to run for?
The study started in September 2013 and recruitment completed in November 2013.

Who is funding the study?
American E-liquid Manufacturing Standards Association (AEMSA).

Who is the main contact?
Dr Konstantinos Farsalinos
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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
N/A

Study information

Scientific Title
Nicotine absorption from electronic cigarette use: comparison between experienced and naive users

Study objectives
We hypothesize that naive electronic cigarette users may use the devices less intensively compared to experienced users; therefore, nicotine is absorbed slower and in lower amounts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Onassis Cardiac Surgery Center, 25/06/2013

Study design
Open-label non randomised clinical trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

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

Interventions
Group 1: Experienced vapers
Group 2: Naive vapers (which were long-term smokers, with at least 5 years smoking duration)

Use of an electronic cigarette device with nicotine-containing liquid for a total of 65 minutes.

Both were given electronic cigarettes and the results will be compared between groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Plasma nicotine levels at 5 min, 20 min, 35 min, 50 min and 65 min of use.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/09/2013

Completion date
15/11/2013

Eligibility

Key inclusion criteria

1. Clinically healthy individuals, both genders, 16-80 years old
2. No history of cardiovascular or other disease
3. Not taking any medications
4. Not pregnant
5. No risk factors for cardiovascular disease (besides smoking)
6. No history of fainting or feeling faint when obtaining blood samples.
7. Daily smokers for at least one year consuming at least 10 cigarettes per day for the group of naive electronic cigarette users.
8. Daily electronic cigarette users of at least one month who had quit smoking for at least one month for the group of experienced electronic cigarette users.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Suspicion of pregnancy
2. History of hematological abnormalitites
3. Inability to provide blood samples
4. Unwillingness to sign informed consent

Date of first enrolment
15/09/2013

Date of final enrolment
15/11/2013

Locations

Countries of recruitment
Greece

Study participating centre
Eslin 12
LAMIA
Greece
35100

Sponsor information

Organisation
American E-liquid Manufacturing Standards Association (AEMSA) (USA)

Sponsor details
P.O. Box 184
Englewood, Ohio
United States of America
45322

Sponsor type
Research organisation

Website
http://www.aemsa.org/

Funder(s)

Funder type
Other

Funder Name
American E-liquid Manufacturing Standards Association (AEMSA)

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?
Results article	results	17/06/2015	21/01/2019	Yes	No