

Nicotine absorption from electronic cigarettes

Submission date 12/02/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/01/2019	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

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
kfarsalinos@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Konstantinos Farsalinos

Contact details
Eslin 12
LAMIA
Greece
35100
+306977454837
kfarsalinos@gmail.com

Additional identifiers

Protocol serial number
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

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Suspicion of pregnancy
2. History of hematological abnormalities
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)

Funder(s)**Funder type**

Other

Funder Name

American E-liquid Manufacturing Standards Association (AEMSA)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes