

# Nicotine absorption from electronic cigarettes

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

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## 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?
<a href="#">Results article</a>	results	17/06/2015	21/01/2019	Yes	No