

Acute effects of electronic cigarette on myocardial function

Submission date 30/07/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/08/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/07/2015	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cigarette smoking has well-established severe side effects on the functioning of the heart, specifically left ventricular myocardial function. Electronic cigarettes have been recently marketed as an alternative to smoking. However, no studies have evaluated the clinical effects of electronic cigarette use. Therefore, the purpose of this study was to find out the effects of electronic cigarette use on left ventricular myocardial function and to compare them with the effects of cigarette smoke.

Who can participate?

Volunteers, healthy smokers and healthy electronic cigarette users can participate in this study.

What does the study involve?

Smokers and electronic cigarette users are the two groups evaluated. An initial heart test (echocardiogram) will be performed in smokers after at least 8 hours of refraining from smoking, alcohol, food and caffeine intake. Then, they will smoke 1 cigarette in 5 minutes and a second echocardiogram will be performed. In electronic cigarette users, an echocardiogram will be performed after at least 8 hours of refraining from electronic cigarette use, alcohol, food and caffeine intake. Subsequently, they will be asked to use an electronic cigarette for 7 minutes. A new echocardiogram will be performed. The two echocardiograms will be compared in both of the groups.

What are the possible benefits and risks of participating?

By taking part in this study there are no risks of physical injury or harm. 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 echocardiogram.

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 December 2011 and recruitment was completed in May 2012.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Konstantinos Farsalinos
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Contact information

Type(s)
Scientific

Contact name
Dr Konstantinos Farsalinos

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Acute effects of using an electronic nicotine-delivery device (electronic cigarette) on myocardial function: comparison with the effects of regular cigarettes

Study objectives
The purpose of this study was to examine the immediate effects of electronic cigarette use on left ventricular function and compare them with the effects of cigarette smoking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the Onassis Cardiac Surgery Center ethics committee, Greece

Study design

Case-control study

Primary study design

Interventional

Secondary study design

Case-control study

Study setting(s)

Other

Study type(s)

Diagnostic

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

Interventions

We asked smokers to smoke 1 tobacco cigarette for 5 minutes and electronic cigarette users to use an electronic cigarette device for 7 minutes. Echocardiograms were performed, before and after this intervention, to evaluate the left ventricular systolic and diastolic function and examine the possibility of changes induced by the intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Changes in left ventricular myocardial diastolic function after smoking and electronic cigarette use assessed by echocardiography, 5 minutes after the intervention

Secondary outcome measures

Hemodynamic changes

Overall study start date

10/02/2012

Completion date

25/08/2012

Eligibility**Key inclusion criteria**

1. Clinically healthy individuals
2. No history of cardiovascular or other disease
3. Not taking medications
4. Not pregnant
5. No risk factors for cardiovascular disease (besides smoking)

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

80

Key exclusion criteria

1. Electrocardiographic abnormalities
2. Echocardiographic signs of myocardial systolic dysfunction
3. Low ejection fraction
4. More than mild valve regurgitation or any other valve disease

Date of first enrolment

10/02/2012

Date of final enrolment

01/05/2012

Locations**Countries of recruitment**

Greece

Study participating centre

ESLIN 12

LAMIA

Greece

35100

Sponsor information**Organisation**

Onassis Cardiac Surgery Center (Greece)

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02gan0k07>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

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	23/06/2014		Yes	No