The health risks of exposure to environmental e-cigarette vapor

Published: 05-10-2015
Last updated: 19-04-2024

The two objectives of the study are:(1) to determine te concentrations of nicotine, propylene glycol, glycerol, formaldehyde, acetaldehyde, acrolein, diacetyl, tobacco-specific nitrosamines and metals (V, Cr, Mn, Ni, Cu, Zn, As, Cd, Sn and Pb) in…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42379

Source
ToetsingOnline

Brief title
health risks of e-cigarette vapour to bystanders

Condition

- Other condition

Synonym
not applicable

Health condition

schade aan de ademhalingswegen, vermindering van het aantal leukocyten en verhoogd risico op kanker.

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: het ministerie van Volksgezondheid;Welzijn en Sport (VWS)

Intervention

Keyword: E-cigarettes, environment, health risks

Outcome measures

Primary outcome

Ther most important outcomes will be:

(1) The concentration of the following components of exhaled e-cigarette

vapour: nicotine, propylene glycol, glycerol, formaldehyde, acetaldehyde,

acrolein, diacetyl, tobacco-specific nitrosamines and metals (V, Cr, Mn, Ni,

Cu, Zn, As, Cd, Sn and Pb) in exhaled e-cigarette vapour.

(2) The rate at which e-cigarette users release vapour into their environment.

Secondary outcome

not applicable

Study description

Background summary

E-cigarette use increases rapidly in the Netherlands. In a recent survey conducted among Dutch e-cigarette users, a significant fraction of respondends indicated that limiting the health risks to themselves (57%) and others (25%) had been motives for using e-cigarettes (instead of regular tobacco cigarettes). In an earlier study we have made an assesment of the health risks e-cigarettes pose to users. This revelead that e-cigarette vapour contains several harmful components in concentrations that can be detrimental to the health of users. Possible health effects include damage to the respiratory system, a reduction

in lymfocyte count and an increased risk of cancer.
However, very little is currently known regarding the health risks assocaited with passive exposure to the vapour exhaled by e-cigarette users.

Study objective

The two objectives of the study are:

(1) to determine te concentrations of nicotine, propylene glycol, glycerol, formaldehyde, acetaldehyde, acrolein, diacetyl, tobacco-specific nitrosamines and metals (V, Cr, Mn, Ni, Cu, Zn, As, Cd, Sn and Pb) in exhaled e-cigarette vapour.
(2) to determine the rate at which e-cigarette users release vapour into their environment.

Study design

1) To determine the composition of exhaled air, subjects will be asked to inhale a nicotine-containing e-cigarette vapour, and then to exhale into a setup that allows us to capture the vapour on filters and analyse its composition at a later time.

2) To determine the amount of vapour exhaled by users in a specified amount of time, we will ask subjects to use an e-cigarette ad libitum for some time. We will then measure and record their vaping topology by means of an electronic flowmeter. We will ask subjects to use their own favourite brand of e-cigarette and liquid to approximate their normal vaping behaviour as closely as possible,

Intervention

Participants will be asked to take 30 puffs from a popular type of electronic cigarette filled with a nicotine-containing, tobacco flavoured e-liquid

Study burden and risks

Subjects will be asked to travel to the RIVM in Bilthoven and to take approximately 40 puffs from e-cigarettes filled with a nicotine-containing liquid. The number of puffs and the nicotine concentration in this study is similar to that consumed daily by an average user.

Earlier research, both our own and that of others, has shown that e-cigarettes are not harmless. Nicotine is harmful and addictive, and the vapour contains several other compounds that can be detrimental to health. However, the subjects participating in this study are experienced e-cigarette users that have been using nicotine-containing e-cigarettes on a daily basis for at least 3 months prior. Therefore, the level of exposure to harmful vapour will be

small compared to the amount they are already exposed to daily outside of the context of our study.

Our study should provide a good assesment of the health risks associated with passive exposure to e-cigarette vapour. Current knowledge in this area has remained very limited to date, while 25% of e-cigarette users indicated in a recent survey that limiting the health risks to other people in their environment has been an important motive for them to start using e-cigarettes (instead of tobacco cigarettes).
The results could prompt users to alter their behaviour and lead governments to implement new regulations (if necessary), reducing adverse health on a large scale.

In our opinion, therefore, the additional health risks and inconvenience caused by our study are justified in light of the potential health benefits on a population scale.

Contacts

Public
RIVM

Rijnstraat 50
Den Haag 2515 XP
NL
Scientific
RIVM

Rijnstraat 50
Den Haag 2515 XP
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects must be between 18-55 years old.
2. Subjects must he using e-cigarettes daily with an e-liquid containing >6 mg/ml nicotine for 3 months or longer.

Exclusion criteria

1. Subjects may not have experienced adverse effects from using e-cigarettes.
2. Subjects must not be lactating, pregnant, or have plans to get pregnant

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	27
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-10-2015
Application type:	First submission

Review commission: METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53471.081.15