Nicotine salts

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20501

Source
NTR

Brief title
Nicotine salts

Health condition

Not applicable

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Perceived liking, nicotine intensity (buzz), harshness/throat hit, pleasantness of throat hit, and willingness to use again (on a 100-unit VAS scale) for nicotine free-base and nicotine salts e-liquids.
Puffing intensity (average puff number, puff duration and time between puffs for nicotine free-base and nicotine salts e-liquids.

Secondary outcome

- Gender, smoking status (dual use), liquid order and used to nicotine salts.
- Difference in liking, nicotine intensity (buzz), harshness/throat hit, pleasantness of throat hit over time (after 5 min versus after 10 min).
- Correlation coefficients between liking, intensity, harshness/throat hit, pleasantness of throat hit, and nicotine buzz.

Study description

Background summary

Inhalation facilitation is not allowed according to the European TPD, as this will increase the product appeal and addictive potential of e-cigarettes, especially among non-smokers, who are not used to the harsh taste and throat irritation of nicotine. In the US, JUUL e-cigarettes and similar devices led to a fast increase of e-cigarette use among young non-smokers. JUUL is a discrete vaporizer that looks like a USB drive, with prefilled pods containing nicotine salts instead of free-base nicotine. JUUL entered the US market in 2015 and, in 2018, it captured more than half the e-cigarette market. The rapid increase in use and large popularity, especially among young people, is concerning. However, in the US, nicotine concentrations in liquids are often much higher than in Europe, since in Europe a nicotine cap of 20 mg/mL is prescribed by the TPD. Therefore, the Dutch Ministry of Health, Welfare and Sports (VWS) commissioned a study to assess whether nicotine salts in concentrations relevant for the Dutch market will facilitate inhalation. To resemble real-life conditions as close as possible, we will carry out a home-use study where participants will use their own refillable e-cigarette device, and vape in a naturalistic manner.
The objective of the study is to determine if vape resulting from e-liquids with nicotine salts is more appealing, tastes milder and is easier to inhale than vape from e-liquids with free-base nicotine.
This study has a within-subjects design. The study consists of a pick-up moment and four vaping sessions (two try-out sessions and two live sessions with a researcher). Recruitment consists of a screening survey (2 min) among recipients in the database of consumer agency Essensor, followed by selection of subjects according to the inclusion criteria. The pick-up consists of signing informed consent and picking up the study e-liquids at the Essensor office. The try-out session gives the subject the opportunity to get acquainted with the first study e-liquid (Day 1). The live session (Day 2), hosted by Essensor, consists of a short introduction of the session during which the subject starts vaping. Next, participants are instructed to vape ad libitum while watching a neutral video (5 min), to simulate a naturalistic vaping moment. After that video, the subject scores liking, nicotine intensity (buzz), harshness of throat hit, and pleasantness of throat hit on a 100-unit VAS scale. Next, the video continues for another 5 min, after which the subject scores liking, nicotine intensity (buzz), harshness of throat hit, pleasantness of throat hit and willingness to use this e-liquid again. As the sessions are recorded, the puffing topography (i.e. puff number, puff duration, puff interval) can be determined afterwards. This Day 2 is followed by another try-out session of the second study e-liquid on Day 3, followed by a live session (similar to Day 2) on Day 4. At the end of the live session at Day 4, subjects answer questions about their vaping status.

The study population consists of 84 healthy male and female volunteers (aged 18-70) used to vaping e-liquids with nicotine more than once per week.
The intervention is that the subjects will vape two tobacco flavored e-liquids; one with free-base nicotine and one with nicotine salts (12mg/mL of nicotine). Half of the group will start with the nicotine salts e-liquid and the other half with the free-base e-liquid (randomized) and subjects and researcher do not know which of the two study e-liquids they are vaping (double-blinded).
Main study parameters/endpoints are 1) perceived liking, nicotine intensity (buzz), harshness/throat hit, pleasantness of throat hit, and willingness to use again (on a 100-unit VAS scale) for nicotine free-base and nicotine salts e-liquids, and 2) intensity of use, as measured by puff number, puff duration and time between puffs for nicotine free-base and nicotine salts e-liquids.
The subjects burden in terms of time is 1,5 hours (pick-up and signing informed consent, two try-out sessions, two live sessions and a short survey). There are no additional risks as the e-liquids in the study are commercially available. Furthermore, the nicotine concentration used in the study (12mg/mL) is similar to the concentration of their usual e-liquids and below the maximum allowed concentration (20 mg/mL). Therefore, we consider the knowledge obtained and possible societal and health implications of this study to outweigh the individual burden and risks.

Study objective

We expect to find that e-liquids with nicotine salts taste milder and are easier to inhale than e-liquids with free-base nicotine. More specifically, we hypothesize that e-liquids with nicotine salts, in comparison to free-base e-liquids:

1. are scored higher on liking on a 100-Unit VAS scale;
2. are scored higher on nicotine buzz on a 100-Unit VAS scale;
3. are scored lower on harshness/throat hit on a 100-Unit VAS scale;
4. are scored higher on pleasantness of throat hit on a 100-Unit VAS scale;
5. are scored higher on willing to use again on a 100-Unit VAS scale;
6. are puffed more intensely, as reflected in number of puffs and average puff duration during the session.

Study design

Day 1: During live session: measurement of puff behavior 2 x 5 min + 2 x short survey
Day 3: During live session: measurement of puff behavior 2 x 5 min + 2 x short survey.
1 longer survey at the end of the live session. (See Interventions)

Intervention

Subjects use their own refillable e-cigarette for the home-use test with the study e-liquids. The type of e-cigarette is registered by the Essensor researcher. The settings of the e-cigarette can be chosen by the subject (if applicable), will be registered and should be used during the entire study. The subjects will consume two different study e-liquids in the home-

use test: study e-liquid 1 and study e-liquid 2. The study e-liquids are made of commercially available nicotine booster (free-base nicotine or nicotine salts) and tobacco flavor aroma. The nicotine level of both study e-liquids will be 12 mg/mL.
Subjects will fill in 3 surveys during the entire experiment.
1. Short survey. During the live session, after 5 minutes, the subjects need to fill in 4 questions about perception of the liquids assessed (i.e. liking, nicotine intensity (buzz), harshness of throat hit, and pleasantness of throat hit).
2. Short survey. During live session after 10 minutes, the subjects need to fill in 5 questions about perception of the liquids assessed (i.e. liking, nicotine intensity (buzz), harshness of throat hit, pleasantness of throat hit and wanting to use again) (similar to point 2).
3. Survey. After finishing the second live session (Day 4), subjects receive 8 additional questions about smoking and vaping status.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Aged 18 to 70 years at the time of inclusion
- Vaping at least more than once per week
- Used to vape e-liquids with nicotine (>1 mg)
- Generally healthy as self-reported
- Owning and using a refillable e-cigarette
- Owning and familiar with using a computer (with webcam and microphone)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Women only: pregnant or lactating
- Experiences negative health effects of vaping or smoking
- Asthma or other lung disease

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	84
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9408
CCMO	NL77340.068.21

Study results