Effect of ammonium compounds in tobacco on the nicotine absorption in smokers

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To determine if adding ammonium to tobacco of cigarettes increases nicotine absorption (amount and speed) in blood of experienced (chronic) smokers.

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

Summary

ID

NL-OMON30221

Source
ToetsingOnline

Brief title
Human ammonium study

Condition

- Other condition

Synonym
Addiction, habituation

Health condition

verslaving

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ammonium, cigarettes, cross-over trial, nicotine

Outcome measures

Primary outcome

The endpoint is nicotine and cotinine determinations in blood. Secundairy parameters are nicotine and cotinine determinations in saliva, exposure-related parameters (carboxyhaemoglobin, NNAL en NNAL-glucuronide, thiocyanate en acetonitrile) in blood, exposure-related parameters (acetonitrile and nitric monoxide) in exhaled breath, and bloodpressure and heartfrequency.

Secondary outcome

Secundairy parameters are nicotine and cotinine determinations in saliva, exposure-related parameters (carboxyhaemoglobin, NNAL en NNAL-glucuronide, thiocyanate en acetonitrile) in blood, exposure-related parameters (acetonitrile and nitric monoxide) in exhaled breath, and bloodpressure and heartfrequency.

Study description

Background summary

Several ingredients are added to tobacco during manufacturing of cigarettes to improve the taste, combustion, or increase the storage life. According to the tobacco industry ammonium compounds are added for their flavouring properties. However, recently it has been demonstrated that ammonium compounds might

increase the amount of nicotine absorbed during smoking.

Study objective

To determine if adding ammonium to tobacco of cigarettes increases nicotine absorption (amount and speed) in blood of experienced (chronic) smokers.

Study design

Experienced smokers smoke two cigarettes from two different brands, that are commercially available on the Dutch market. Both brands contain the same amounts of tar and nicotine, but differ in ammonium-content. The study will be performed according to the cross-over design, in other words, a person smokes cigarette A in the morning and, after a wash-out period, cigarette B in the afternoon. Testcigarettes will be smoked via a tube, so volumes will be the same per puff. In addition, studypersons need to smoke according to a regime: every 60 sec an inhalation of 55 ml in 2 sec, then a 2 sec breath-hold, after which smoke can be exhaled. From each cigarette, 6 puffs will be taken, after which the cigarette will be extinguished. Before, during and after smoking the test-cigarette, blood (2 times 12 ml and 6 times 3 ml) will be drawn via a venous catheter (in total 84 ml), and saliva will be collected with a cotton swab. Study persons are also connected to a real-time bloodpressure and heartfrequency monitor.

Intervention

Smoking of a cigarette with a high ammonium-content and a cigarette with a low ammonium-content.

Study burden and risks

Volunteers need to visit the Slotervaarthospital once. Smoking the night before until the study is not allowed. The study comprises 2 times one-and-half hour investigation. Between the investigations is a 4 hour break, wherein smoking is not allowed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18-50 years of age; Good health; Smoking more than 20 cigarettes or fine-cut tobacco (roll-yor-own) per day; Inhale during smoking.

Exclusion criteria

Use of medicines, except oral contraconceptives or replacement hormones; Use of nicotin-containing products; Pregnancy or lactation; History of psychiatric problems/conditions; History of cardiac and pulmonary conditions.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	48
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL14930.048.06