Memory reconsolidation: a new treatment approach towards nicotine addiction.

Published: 16-10-2018
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Whether disrupting reconsolidation by a noradrenergic beta-blocker provides long-term relief from nicotine-addiction.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48641

Source
ToetsingOnline

Brief title
New treatment for smoking cessation.

Condition

- Other condition

Synonym
nicotine-addiction, smoking

Health condition

nicotine-verslaving

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: addiction, memory, reconsolidation, smoking

Outcome measures

Primary outcome

Smokingstatus, as assessed by using an online smoking-diary.

Secondary outcome

- breath monoxide assessment;

- urine cotinine levels;

- questionnaires related to withdrawal symptoms.

Study description

Background summary

Smoking is one of the leading causes of preventable death globally. Quitting before the age of 40 reduces the risk of dying from smoking-related diseases by nearly 90%. Given that existing therapies have limited long-term efficacy, there is a pressing need for innovation in the smoking cessation field.

Study objective

Whether disrupting reconsolidation by a noradrenergic beta-blocker provides long-term relief from nicotine-addiction.

Study design

Double-blind randomized placebo-controlled trial.

Intervention

Single reactivation session of smoking-related behavior followed by the

administration of 40 mg of the noradrenergic beta-blocker propranolol.

Study burden and risks

Participants are receiving a short treatment that is expected to diminish their nicotine-addictive behavior. Based on the SPC we expect that propranolol HCl will be well tolerated and do not anticipate any serious adverse events.

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

- aged between18 and 65 years;
- smoking 10 or more cigarettes per day for at least 12 months;

- written approval of participant's own general practitioner for participation.

Exclusion criteria

- cardiovascular diseases or irregular heartbeat;
- hypotension or hypertension;
- pregnancy or breastfeeding;
- epilepsy;
- current state of asthma or COPD, which necessitates medication use.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2020
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	te genereren door farmaceutisch bedrijf
Generic name:	propranolol hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	16-10-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2018-002829-33-NL
CCMO	NL66903.018.18