The influence of vagal nerve stimulation on reward-based selective attention

Published: 24-07-2013
Last updated: 23-04-2024

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Ethical review	Not approved
Status	Will not start
Health condition type	Seizures (incl subtypes)
Study type	Observational non invasive

Summary

ID

NL-OMON38674

Source
ToetsingOnline

Brief title
VNS and selective attention

Condition

- Seizures (incl subtypes)

Synonym
attention, reward sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,KNAW,ERC-2012-AdG - 323413_REWARDVIEW: What you get is what you see: How Reward Determines Perception (PI: Jan Theeuwes)

Intervention

Keyword: attention, reward, vagal nerve stimulation

Outcome measures

Primary outcome

Main parameters of interest are the reaction time differences in the visual search tasks, and alterations of perceived stimulus presentation onset. Both can be used as a measure to indicate the degree of influence of VNS on reward processing and selective attention. Previous and ongoing studies on healthy observers in our groups show a beneficial effect of monetary reward on reaction times in visual search tasks (Hickey et al. 2010) and perceived stimulus onset in the simultaneity judgement task. In the present study we aim to test both whether VNS changes these effects of monetary reward and whether stimulation could actually replace the monetary reward as source for the observed influence on selective attention.

Secondary outcome

not applicable

Study description

Background summary

Vagal nerve stimulation is a relatively new medical therapy in which the central nervous system is stimulated with electrical pulses in order to relieve disease symptoms. In vagal nerve stimulation (VNS), electrical pulses are directed to the left vagal nerve (10th cranial nerve) in the lateral part of the neck via a system that includes neurosurgically implanted electrode leads and a pulse generating pacemaker device. The VNS procedure is already an approved treatment option for treatment resistant epilepsy and depression. Several studies have also shown non-symptomatic beneficial effects of VNS.

These include neuromodulatory characteristics (Engineer et al. 2011) and enhancing effects on cognition and memory (Clark et al. 1999). The precise mechanisms underlying the beneficial effects of VNS are currently not well understood. In order to understand these mechanisms it is important to have a better idea of the non-symptomatic effects of stimulation. It is plausible that the cognitive side effects of VNS are far more reaching including effects on reward processing and visual attention but this has never been tested yet.

Study objective

The objective of our study is to investigate the relationship between electrical stimulation of the central nervous system (VNS) and reward-based selective attention. In order to do so, we will ask subjects to complete a set of tasks on a standard computer. These tasks, aimed at probing the reward-driven distribution of selective attention are already used in other reward studies (some of which in our own lab), where money is given as a reward. In our study, we will both repeat these findings with a monetary reward in the presence and absence of stimulation, and we will perform a version of the task in which the monetary reward following a correct response is replaced by acute vagal nerve or deep brain stimulation. With this approach we wish to determine whether the direct stimulation of the reward center in the brain interferes with the effects of a monetary reward and/or has by itself an effect that is comparable to the delivery of monetary rewards. This research will provide more insight into the effects of VNS on neuronal processes, which might eventually extend the scope of this therapy.

Study design

Patients that will perform the experiments are all treated with VNS. We will ask patients to perform the tasks at the AMC. We will conduct the experiments in separate blocks, lasting in total approximately 2 hours. We aim to find an effect of VNS on reward processing and selective visual attention. All tasks that we intend to use in this patient study have already been conducted by healthy observers, revealing clear effects of reward on the distribution of visual attention. We will first repeat the basic experiment in the VNS patients in the absence of stimulation to obtain a baseline measure of the effect shown in the healthy observers. We well then move on to test the impact of stimulation on the underlying reward-based attention mechanisms.

Study burden and risks

The burden for the patients will consist of visiting the AMC to conduct visual search and simultaneity judgment tasks for 2 hours. To our knowledge, there will be no additional risks associated with our experiments. Participating patients will not benefit directly from the experiments. They will, however, contribute to the extension of knowledge about vagal nerve stimulation in

future patients. In addition, they will help to improve understanding of reward processing in the human brain.

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

Capability of giving informed consent - Patients implanted with a VNS device for the treatment of epilepsy - Age > 18 years

Exclusion criteria

Incapability of participating in the experiments as judged by the investigators - Inability to

turn off the stimulators for the duration of the experiment on clinical grounds

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Not approved

Date:	24-07-2013
Application type:	First submission
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
CCMO	NL44598.018.13