Enhancing Motor Learning with a Single Dose of Modafinil or Fluoxetine

Published: 03-07-2015 Last updated: 16-04-2024

1) to identify the effect of manipulating the electrical synapses in the IO on motor learning in healthy individuals during cerebellar specific motor adaptation tasks. 2) to identify the effect of manipulating the subthreshold oscillations in the IO...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON42762

Source ToetsingOnline

Brief title Improving motor learning

Condition

• Movement disorders (incl parkinsonism)

Synonym

n.a.

Research involving Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: Gap junctions, Inferior Olive, Rehabilitation, Serotonin

Outcome measures

Primary outcome

The main objective of the study is to determine the effect of modafinil and fluoxetine on motor learning in healthy individuals. The participants will be subjected to two different cerebellar specific motor adaptation paradigms: the random saccade adaption task (motor timing independent) and the random smooth pursuit adaptation task (motor timing dependent). The motor learning capacity will be determined by quantifying the velocity and gain of adaptation. A minimal drug-induced improvement of the motor learning capacity by 10% is considered clinically relevant.

Secondary outcome

n.a.

Study description

Background summary

Motor impairments are the most common deficits caused by stroke. Although standard rehabilitation efforts are used to facilitate recovery after stroke, additional interventions are necessary to further improve/regain motor function and avoid limitation in mobility. Improving motor learning capacity could aid this rehabilitation process. Motor learning is in the brain mainly regulated the olivo-cerebellar system. The Inferior olive (IO) is one of the major information gateways that relay motor error signals to the cerebellum. Neurons of the IO have very intriguing properties; they receive sensory information (from the body) as well as feedback information from the cerebellum, they communicate mainly with each other via electrical synapses and they generate subthreshold oscillations. The IO can theoretically be manipulated in two ways in order to facilitate motor learning: 1) the electrical transmission between olivary neurons can be enhanced by using pharmacological modulators of electrical synapses, and 2) the amplitude of the subthreshold oscillations can be reduced by using a pharmacological serotonergic intervention. Modafinil is known to enhance electrotonical coupling between olivary neurons and serotonin is known to reduce the subthreshold oscillation of olivary neurons (and we expect that fluoxetine will do the same). Although both drugs intervene on another olivary property/mechanism, they both could potentially shorten the rehabilitation time and help to achieve higher levels of motor performances. In this study, we will investigate the effect of modafinil and fluoxetine (via pharmacological manipulation of the IO) on motor learning in healthy individuals during a cerebellar specific motor adaptation tasks.

Study objective

1) to identify the effect of manipulating the electrical synapses in the IO on motor learning in healthy individuals during cerebellar specific motor adaptation tasks. 2) to identify the effect of manipulating the subthreshold oscillations in the IO on motor learning in healthy individuals during cerebellar specific motor adaptation tasks.

Study design

Double-blind randomize placebo-controlled study

Study burden and risks

The subjects have to visit the Erasmus MC for 2 times and for a total of 6 hours (modafinil group) or 12 hours (fluoxetine group). They have to fill in two questionnaires, do four motor tasks and one cognitive task. Subjects that are in the modafinil group have to wait (in the relax room) for two hours, whereas the fluoxetine group have to wait 5 hours before the start of the motor- and cognitive tasks. The total duration of all tasks will be around 1 hour. Neither the behavioural tasks nor the single-dose of modafinil or fluoxetine does cause a significant discomfort or risk for the subject. The subject*s receive a financial compensation for expenses made due to participation.

Contacts

Public Erasmus MC

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NL **Scientific** Erasmus MC

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Healthy Male Aged 18-55 years Informed consent obtained

Exclusion criteria

History of neurological or psychiatric disorders History of neurosurgery History of Sleep disorders History or evidence of renal, gastrointestinal, hepatic or hematologic abnormalities Using acute or chronic psychoactive drugs Alcoholism Smoking

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-02-2016
Enrollment:	166
Туре:	Actual

Ethics review

Approved WMO	
Date:	03-07-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	03-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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 CCMO **ID** NL52849.078.15