Enhancing Motor Learning with a Single Dose of Levodopa

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To identify the role of dopamine transmission in the GC layer on motor learning in healthy individuals during cerebellar specific motor adaptation tasks.

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

Summary

ID

NL-OMON46724

Source
ToetsingOnline

Brief title
Improving motor learning II

Condition

- Other condition

Synonym
n.a.

Health condition

revalidatie na herseninfarct/bloeding

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: cerebellum, dopamin, granule cells, revalidation

Outcome measures

Primary outcome

The main objective of the study is to determine the role of dopamine on motor learning in healthy individuals. The participants will be subjected to two different cerebellar specific motor adaptation paradigms: the inward saccade adaptation task and the visuomotor adaptation task. The motor learning capacity will be determined by quantifying the velocity and gain of adaptation. The motor timing, motor tremor, motor strength and attention task are control experiments that allow us to put the output parameters of adaptation tasks in the correct perspective.

Secondary outcome

n.a.

Study description

Background summary

Motor impairments are the most common deficits caused by stroke. Although standard revalidation 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 the rehabilitation process. Motor learning is in the brain mainly regulated by the olivo-cerebellar system. The Granule cell (GC) layer is one of the major information gateways that relay sensory signals to the cerebellar cortex. The GC layer has very intriguing properties; they receive sensory information (from the body) and express many modulatory receptors. They integrate and filter the sensory information from the body before sending it to the cerebellar cortex. The GC layer can theoretically be manipulated in order to facilitate motor learning by using pharmacological modulators. Activation of

modulatory receptors in the GC layer can alter the information flow towards the cerebellar cortex. In the GC layer dopamine receptors are present. Enhanced levels of dopamine in the GC layer might facilitate the information flow to the cerebellar cortex and consequently accelerate the process of motor learning. Currently, it is still unknown what the exact role is of dopamine in the human cerebellum. Levodopa/carbidopa can be used as a tool to enhance the levels of dopamine in the GC layer and allow us to investigate which elements of the motor learning process are regulated by dopamine. Although the drug intervene on other receptors in the brain, it could potentially shorten the revalidation time and help to achieve higher levels of motor performances. Furthermore, manipulating the GC layer in this ways will also give us more insight in the functional capacity of the GC layer during motor performance and learning.
In this study, we will investigate the role of dopamine transmission (via pharmacological manipulation of the GC layer using levodopa/carbidopa) on motor learning in healthy individuals during cerebellar specific motor adaptation tasks.

Study objective

To identify the role of dopamine transmission in the GC layer on motor learning in healthy individuals during cerebellar specific motor adaptation tasks.

Study design

Double-blind randomized placebo-controlled cross-over design study

Intervention

Each participant receives once a dose of Levodopa / Carbidopa (100mg / 25mg) and once a placebo. The two intake moments are separated for at least a week.

Study burden and risks

The subjects have to visit the Erasmus MC for 2 times and for a total of 4 hours. They have to fill in two questionnaires, do five motor tasks and one cognitive task. Subjects have to wait (in the relax room) for 30 minutes 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 levodopa/carbidopa does cause a significant discomfort or risk for the subject. The subject*s receive a financial compensation for expenses made due to participation.

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

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-05-2018
Enrollment:	42
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Sinemet plus 25 mg/100mg tablets
Generic name:	Levodopa/Carbidopa 100mg/25mg
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	02-07-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	10-07-2018
Application type:	First submission
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	ID
EudraCT	EUCTR2018-001766-41-NL
CCMO	NL64558.078.18