The role of dopamine and oxytocin in individual and social performance monitoring

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

Summary

ID

NL-OMON50126

Source
ToetsingOnline

Brief title
Dopamine, oxytocin and performance monitoring

Condition

- Other condition

Synonym
cognitive performance (performance monitoring)

Health condition

cognitieve prestatie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Dopamine (L-DOPA), Oxytocin, Social performance monitoring

Outcome measures

Primary outcome

Brain activation during the various tasks and scans (resting state scans, Cannonball task, Prosocial Probabilistic Learning task, Working Memory task) across the different (pharmacological) conditions.

Secondary outcome

Behavioural outcomes such as accuracy and self-reported responsibility levels in the different tasks and scans (resting state scans, Cannonball task, Prosocial Probabilistic Learning task, Working Memory task) across the different (pharmacological) conditions.

Study description

Background summary

Researchers have started to unravel the neurochemistry involved in performance monitoring, which is the ability to detect our errors and act upon them, and in social behaviour. Recently, we demonstrated that administration of the neuropeptide oxytocin enhances processing of social mistakes, suggested to derive from oxytocin-induced changes in perceived responsibility. Other research employing pharmacological manipulations from our and other labs has repeatedly established a crucial role for the neurotransmitter dopamine in non-social performance monitoring. Yet, the role of dopamine in performance monitoring in a social context remains unclear. Such insights are important because recent theoretical accounts and animal studies have indicated that both oxytocin and dopamine are involved in socially relevant processes, such as

reward processing and that especially the crosstalk between the two is essential for facilitating positive social interactions. Pharmacological studies directly comparing the effects of oxytocin and dopamine on social performance monitoring in humans, however, are crucially missing.

Study objective

The aim of this study is to improve our understanding of the mechanisms underlying altered social performance monitoring from a pharmacological perspective by directly comparing the effects of dopamine and oxytocin on individual and social performance monitoring.

Study design

The study will employ a double-blind placebo-controlled cross-over design.

Intervention

Oxytocin, L-DOPA, or placebo will be administered in randomized order over the course of three sessions. After administration, resting state and structural scans will be made and participants will perform three computerized tasks in the magnetic resonance imaging (MRI) scanner: the Cannonball task, the Prosocial Probabilistic Learning task and the Working Memory task.

Study burden and risks

There are no known risks associated with participating in fMRI studies. fMRI is a non-invasive technique and numerous adults have undergone MRI studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the participant's request. The only absolute contraindications to MRI studies are metal implants, intraocular metal and heart arrhythmia. Relative contraindications include claustrophobia. Subjects who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded. There are no known risk associated with the single administration of intranasal oxytocin and L-DOPA in healthy volunteers. Protocols that employed the same dosages of L-DOPA and oxytocin administration in healthy volunteers have been previously approved by the CME of the LUMC (see e.g., P15.116; P11.200). Although there is no direct benefit, the proposed research is expected to make a significant contribution to our understanding of the neurochemical mechanisms of individual and social performance monitoring, processes that are of critical importance for safe, flexible and adaptive (social) behaviour.

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, right-handed males between age 18 and 35 with no history of neurological disorder/disease, no substantial psychiatric history, and no counter-indications to MRI will be included in this study.

Exclusion criteria

Participants should meet none of the following exclusion criteria:
- History of medication or drugs within 1 month prior to the start of treatment with trial medication with the exception of occasional use of paracetamol.
- Previous experience of allergic reaction upon administration of a drug.
- Use of hayfever medication

- Medical or surgical history that in the investigator*s view may significantly affect the outcome of the trial; such as severe visual impairment
- Significant history of head trauma, premature birth, or learning disabilities.
- Heart arrhythmia (including pacemaker/ICD), glaucoma, hypertension.
- Clinically significant history of abnormal cardiovascular, endocrine, psychiatric, neurological or hematological disease.
- Febrile illness within 3 days before the first dose
- Fever or cold within 2 days before the experiment
- Participation in another drug study within 3 months preceding participation in the current study.
- Intake of more than 3 units of alcohol / day
- Smoking more than 5 cigarettes / day
- Inability to understand the nature and extent of the trial and the procedures required.

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:	Recruitment stopped
Start date (anticipated):	30-01-2020
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sinemet 62,5 tablets
Generic name:	levodopa/carbidopa

Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Syntocinon 40 IE/ml nasal spray, solution
Generic name:	oxytocin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	07-03-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	04-10-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	02-12-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-06-2020
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2018-004560-60-NL
CCMO	NL68645.058.19