Come closer: a neurobiological analysis of the prosocial effects of MDMA

Published: 23-12-2010
Last updated: 15-05-2024

In this study we will assess these prosocial effects in an objective way i.e. by means of computer tasks and we will investigate the role of two potential mediators and the role of a genotype variant in the mechanism underlying prosocial behavior....

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

Summary

ID

NL-OMON36227

Source
ToetsingOnline

Brief title
MDMA, oxytocin and prosocial behavior

Condition

- Other condition

Synonym
disturbed social interactions and empathy

Health condition

sociaal en cognitief functioneren

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 5-HT1a, MDMA, Oxytocin, Prosocial

Outcome measures

Primary outcome

- Dependent variables of the empathy and social interaction tasks

- Treatment concentrations and oxytocin concentrations in the blood

Secondary outcome

Dependent variables of the control task: word learning task

Study description

Background summary

The neurobiological mechanism underlying prosocial behaviour (PSB) is yet not known. Fundamental knowledge about this mechanism could lead to new input for researchers seeking new insights into the biological mechanism of diseases in which prosocial behaviour is lacking, such as autism spectrum disorder. Additionally, knowledge about the mechanism underlying this positive kind of behavior will also provide insights about why users proceed into repeated (problematic) drug use.
In the current proposal the partydrug ecstasy (MDMA) will be used to induce a prosocial state. The rationale for chosing MDMA is that MDMA differentiates itself from other types of psychostimulants by its unique effects on social behaviour. Acutely, it induces positive effects on social behaviour, referred to as prosocial effects i.e. subjective feelings of closeness to, and openness towards others, emotional warmth, enhanced well being, contentment, empathy and euphoria. To date, these positive effects on social behaviour have almost exclusively been assessed by means of self-reports or questionnaires. Besides this lack of objective data, the mechanism underlying these effects is not known.

Study objective

In this study we will assess these prosocial effects in an objective way i.e. by means of computer tasks and we will investigate the role of two potential mediators and the role of a genotype variant in the mechanism underlying prosocial behavior.

Main questions and hypotheses:
1) We would like to investigate the role of the hormone oxytocin in the mechanism underlying MDMA-induced prosocial behavior. We hypothesize that oxytocin will mimic MDMA-induced prosocial effects. This will be investigated by comparing task performance after treatment with MDMA with that after treatment with oxytocin and with placebo. Oxytocin concentrations after treatments will also be assessed in the blood and correlated with performance measures.

2) We would like to investigate the role of the 5-HT1a receptor in the mechanism underlying MDMA-induced prosocial behavior. We hypothesize that the 5-HT1A receptor will block the occurence of prosocial effects after MDMA intake. This will be investigated by comparing task performance after treatment with MDMA alone with performance after treament with the MDMA-5-HT1a receptor blocker combination and with placebo.

Minor question and hypothesis:
3) We would like to investigate the role of the serotonin transporter genotype variants in the strength of MDMA-induced prosocial effects. We hypothesize that MDMA users carrying the fast working SERT genotype variant (LaLa) will experience more pronounced prosocial effects compared with the users carrying the slow working variant. This will be investigated by including the genotype variant as a dichotome variable (slow vs fast working variant) in the statistical analysis.

Study design

Design:
The study will be conducted according to a double blind, placebo controlled, crossover design with 4 treatment conditions on four occasions, separated each by a minimum of 7 days washout.

Treatments:
Treatments will consist of MDMA (75mg) alone or in combination 5-HT1A receptor blocker, oxytocin, and placebo . Treatment orders will be randomized by means of a Latin Square. All treatments will have matching placebos.

MDMA (75mg) will be administered as a capsule. The 75mg-dose is based on previous acute studies. Peak plasma levels are reached within 90 minutes. Oxytocin (Syntocinon®) will be administered intranasally. This neuropeptide crosses the blood-brain barrier reliably after intranasal administration. The spray will be administered four times with a delay of 45s between

administrations + two additional administration in between testblocks. Each administration will consist of one inhalation of the spray into each nostril. Each inhalation will contain approximately 4 international units (IU) (total: 48 IU). Peak concentrations will be reached 45 minutes after administration. The 5-HT1A receptor blocker (Pindolol; Visken® 20 mg) will be administered as a capsule. Peak plasma levels are reached 60*post-administration; t1/2= 3 to 4 hours.

Intervention

Administration of treatments (See study design) and collection of a blood sample each test day to determine treament concentrations and oxytocin concentrations in the blood.

Study burden and risks

The risks are confined to possible side effects of the treatments: MDMA, Oxytocin (Syntocinon) and the 5-HT1a blocker (Visken). Subjects are MDMA users and therefore familiar with possible side effects of MDMA.

Study burden in total: 18.5 hours, spread over minimally 5 weeks.

Contacts

Public
Universiteit Maastricht

P.O.Box 616
6200 MD Maastricht
NL
Scientific
Universiteit Maastricht

P.O.Box 616
6200 MD Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy volunteers, aged between 18 and 40 years, who have used esctasy/MDMA with a minimum of 3 times ever and a maximum of 200 times and at least once in the last year

Exclusion criteria

never used ecstasy/MDMA

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):	14-06-2011
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	MDMA
Generic name:	MDMA
Product type:	Medicine
Brand name:	Syntocinon
Generic name:	Syntocinon
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Visken
Generic name:	Pindolol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	23-12-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26647
Source: NTR
Title:

In other registers

Register	ID
Other	2636
EudraCT	EUCTR2010-024161-48-NL
CCMO	NL34859.068.10
OMON	NL-OMON26647