The role of the 5-HT2a receptor in MDMA-induced effects on social cognition and prosocial behaviour

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The aim of this study is therefore to investigate the role of the 5-HT2a receptor in the MDMA-induced effects on social behaviour.

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

Summary

ID

NL-OMON37277

Source
ToetsingOnline

Brief title
MDMA, 5-HT2aR and PSB

Condition

- Other condition

Synonym
Disturbed social interactions and emapthy

Health condition

Sociaal gedrag en cognitief functioneren

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 5-HT2a, empathy, Ketanserin, MDMA

Outcome measures

Primary outcome

Dependent variables of cognitive and affective emapthy scales and tasks

Secondary outcome

- Dependent variables of social interaction task, attitudes task, memory

- Drug and hormone concentrations in the blood

Study description

Background summary

The neurobiological mechanism underlying prosocial behaviour is yet not known. Fundamental knowlegde 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.

In the current study, the prosocial partydrug ecstasy (MDMA) will be used to induce a prosocial state. We know, from previous studies that MDMA induces an increase in emotional empathy and that this effect is not attributable to the effects of MDMA on the 5-HT1a receptor. New evidence suggests that the 5-HT2a receptor might play a role in this mechanism.

Study objective

The aim of this study is therefore to investigate the role of the 5-HT2a receptor in the MDMA-induced effects on social behaviour.

Study design

Design:

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

Treatments:
Treatments will be: MDMA-75 mg, Ketanserin-40 mg, MDMA-75 mg + Ketanserin-40 mg, placebo. Both MDMA and ketanserin will be administered orally as a capsule. Both treatments will have matching placebos (= that will be identical in smell, color and form and will be indistinguishable from the active treatments).

The dosage of MDMA (75 mg) and that of ketanserin (40 mg) are based on previous acute studies. Concentraties in the blood will reach peak plasma concentrations at 90 minutes after intake of MDMA and between 1/2-2h after intake of ketanserin.

Intervention

Administration of treatments (see study design) abd collection of a blood sample each testday to determine durg and hormone concentrations in the blood

Study burden and risks

The risks are confined to possible side effects of the treatments: MDMA and ketanseri. Subjects are ecstasy/MDMA users and are therefore familiar with possible side effects of MDMA.

Study burden in total: 18 hours, spread over minimally 5 weeks.

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 volunteers, aged between 18-35 years, who have used MDMA/Ecstasy with a minimum of 3 times ever and a maximum of 200 times, and at least one during the past year.;(Also see page 14 of the research protocol)

Exclusion criteria

Never used ecstasy/MDMA.;(Also see page 14-15 of the research protocol)

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):	30-01-2013
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ketanserin
Generic name:	Ketanserin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	MDMA
Generic name:	MDMA

Ethics review

Approved WMO Date:	10-12-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-03-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-03-2013
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: 29427
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-005168-82-NL
CCMO	NL42465.068.12
Other	NTR TC 3691
OMON	NL-OMON29427