MDMA en prosociaal gedrag: De rol van de 2a-serotonine receptor.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29427

Source
Nationaal Trial Register

Brief title
MDMA5-HT2aRPSB

Health condition

Neurobiological mechanism underlying MDMA-induced prosocial behaviour

Sponsors and support

Primary sponsor: Maastricht University, K. P. C. Kuypers
Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

Cognitive and affective empathy.

Secondary outcome

1. Social interaction (trust, reciprocity);

2. Implicit attitudes;

3. Processing of affective sounds;

4. Verbal memory.

Study description

Background summary

Rationale:

MDMA exerts positive effects on social behaviour. The neurobiological mechanism underlying these effects is to date not known. There is some evidence that the 5-HT2a receptor might play a role in this mechanism. The fundamental knowledge that is generated by this study can be implemented in research into the neurobiology of certain diseases in which prosocial behaviour or empathy is lacking, e.g. autism spectrum disorders, social anxiety disorder.

Objective:

First, we would like to investigate the effects of MDMA on social cognition and interaction by means of paradigms which take context into account. Second, we would like to investigate the role of the 5-HT2a receptor in these effects. We hypothesize that (1) the MDMA effect on prosocial behavior is context dependent (e.g. influence by ‘extra’ social information and importance of the reward) and that (2) these effects will be absent when MDMA is combined with ketanserin.

Study design & Intervention:

Both aims will be accomplished by conducting a four-way crossover study including single doses and combinations of MDMA-75mg and the 5-HT2a blocker ketanserin-40 mg in order to study the effects of the substances alone and the effects of MDMA after blockade of the 5-HT2a receptors.

Study population:

Participants will be maximally twenty-four (N=20 + 4 drop-outs) recreational ecstasy users (3 < lifetime use <200) aged between 18 and 35 years. All subjects will be medically screened.

Main study parameters/endpoints:

Main study endpoints will be subjective and objective measures of cognitive and affective empathy. Tasks to assess this are the inter-reactivity index and the multifaceted empathy test.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participants will go through 4 sessions of 4h15'. The load for a subject during a test day is restricted to (1) taking study treatments, (2) taking 3 blood samples, (3) filling out questionnaires and doing computer tasks (duration: ± 75 minutes). During the periods that they are not tested (breaks), they will be seated in a waiting room were they will be in close contact with one of the researchers. In case they experience (medical) complaints, the medical supervisor will be contacted.

Study objective

We hypothesize that:

1. The MDMA effect on prosocial behavior is context dependent (e.g. influence by 'extra' social information and importance of the reward) and;

2. These effects will be absent when MDMA is combined with ketanserin.

Study design

Prior to participation, subjects undergo a physical examination (blood, ElectroCardioGram). When there is no medical objection for participation, subjects will come for a training day. During this training day they will be explained the procedure of a test day and be familiarized with the cognitive tests in the laboratory.

Test day (Table 4). Upon arrival at 9:00 at our testing facilities, subjects will be screened for drugs, in urine and alcohol, in breath. They will be asked whether they had enough sleep the day before (questionnaire) and whether they abstained from alcohol and caffeinated beverages 24h prior to the testing day. Between 9:00 and 9:30 they will be offered a standard meal, followed by PreTreatment (Ketanserin/Placebo) at 9:30. Just before they receive the PreTreatment, blood samples will be collected and blood pressure and heart rate will be assessed. At 10:00 participants will receive their treatment respectively MDMA or Placebo. In between subjects will be seated in a waiting room, equipped with a TV. At 11:20 a second blood sample will be taken and blood pressure and heart rate will be assessed. Between 11:30-13:00 testing will take place in the laboratory. At the end of the test battery, blood samples will be collected and heart rate and blood pressure will be assessed (See table 4).

The minimum period between successive treatments will be 7 days. Subjects will be compensated for their participation by means of a monetary reward.

Intervention

1. MDMA-75 mg;

2. Ketanserin-40mg;

3. MDMA-75mg + Ketanserin-40 mg;

4. Double placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Experience with the use of MDMA (maximally 200 times in total, minimally 3 times in total; and at least once in the past 12 months): This will be assessed by means of a drug history questionnaire and an interview by the medical supervisor;

2. Age between 18-35 years;

3. Free from medication (except oral contraception);

4. Good physical health as determined by examination and laboratory analysis;

5. Absence of any major medical, endocrine and neurological condition;

6. Normal weight, body mass index (weight/height2) between 18 and 28 kg/m2;

7. Written Informed Consent;

8. Fluent Dutch speaker (as some tasks require this).

Exclusion criteria

1. History of drug abuse (other than the use of MDMA) or addiction;

2. Current or history of psychiatric disorder;

3. Women: Pregnancy or lactation;

4. Cardiovascular abnormalities as indicated by:

A. The medical questionnaire and/or;

B. The standard 12-lead ECG.

5. Excessive drinking (> 20 alcoholic consumptions a week);

6. Hypertension (diastolic> 90; systolic> 140).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-01-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37277
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3536
NTR-old	NTR3691
CCMO	NL42465.068.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37277

Study results

Summary results
N/A