No registrations found.

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

Summary

Source

NTR

Health condition

mdma users, cognition, 5HT

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Neurocognitive measures of memory and impulse control.

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

To determine the role of 5-HT2 and 5-HT1A receptors in learning and memory. It is expected that:

1. An acute dose of MDMA will produce impairments on laboratory measures of learning and memory;

2. MDMA-induced memory impairment will be reversed by coadministration of ketanserin if impairment is related to direct or indirect stimulation of 5-HT2 receptors;

3. MDMA-induced memory impairment will be reversed by coadministration of pindolol if impairment is related to direct or indirect stimulation of 5-HT1A receptors.

Study design

Neurocognitive measures will be taken at Tmax.

Intervention

Subjects will be treated with combinations of:

1. Ketanserin 50mg / MDMA 75mg (treatment 1);

2. Pindolol 20mg / MDMA 75mg (treatment 2);

3. Placebo / MDMA 75mg (treatment 3);

4. Pindolol 20 mg / placebo (treatment 4);

5. Ketaserin 50mg / placebo (treatment 5);

6. Placebo / placebo (treatment 6).

Drugs and placebo will be administered orally in identically appearing formulations. MDMA is administered as a 25 ml solution in bitter orange peel syrup, which is ingested at once. Ketanserin and pindolol will appear in capsule form. Drugs and placebo will be administered using a double dummy technique to synchronize Tmax for all drugs.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 18 and 40 years of age;

2. Experience with the use of MDMA (at least 5 times, of which no less than one in the past 12 months);

3. Free from psychotropic medication;

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/length2) between 18 and 28 kg/m2;

7. Health insurance;

8. Written informed consent.

Exclusion criteria

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

2. Pregnancy or lactation;

3. Cardiovascular abnormalities as assessed by standard 12-lead ECG;

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

5. Smoking (>10 sigarettes a day);

6. Hypertension (diastolic> 100; systolic> 170);

7. Use of psychotropic medication;

8. History of psychiatric or neurological disorder.

Study design

Design

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

Recruitment

NL

Recruitment status :	Other
Start date (anticipated) :	01-03-2010
Enrollment :	18

Type : Unknown

Ethics review

Positive opinion
Date : 03-06-2010

Application type : First submission

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
NTR-new	NL2227
NTR-old	NTR2352
Other	: P34 EPU
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A