# The role of 5-HT2 and 5-HT1A receptors in 3,4-methylenedioxymethamphetamine (MDMA) induced memory impairment and impulsivity.

No registrations found.

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

## Summary

### ID

NL-OMON23877

**Source**
Nationaal Trial Register

**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