

MDMA and memory.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24391

Source

Nationaal Trial Register

Brief title

N/A

Health condition

MDMA induced memory impairment

Sponsors and support

Primary sponsor: Dr J.G.Ramaekers

Dept of Neuropsychology & Psychopharmacology, Faculty of Psychology and Neuroscience, Maastricht University.

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Source(s) of monetary or material Support: Fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

1. Prospective and verbal memory;
2. Performance (behavior) and BOLD;

3. Response (during prospective memory task).

Secondary outcome

RT and no of correct responses.

Study description

Background summary

Prospective memory refers to the realization of delayed intentions and is an ability that is at the heart of goal directed behavior in everyday life. A number of studies have shown that MDMA users perform worse on subjective and objective measures of prospective memory as compared to non drug using controls. Interpretation of these data however may be limited due to polydrug use, psychosocial stressors and increased psychopathology that have been reported in MDMA users. The present study was designed to directly assess the pharmacological effect of MDMA on prospective memory and brain activity in a double-blind, placebo controlled, cross-over study. Twelve recreational MDMA users received MDMA 75mg and placebo and performed an objective prospective memory task during functional imaging in a 3 Tesla MR scanner.

The present study was expected to provide:

1. direct evidence for the association between MDMA and memory impairment;
2. objective assessments of prospective memory function during MDMA intoxication;
3. neural structures critically involved in memory dysfunction during MDMA intoxication.

Study objective

The primary aim of the study is to qualify the neural network underlying memory impairment when performing on two memory tasks after a single dose of MDMA, compared to placebo.

Study design

Assessments between 1.5 and 2.5 hrs post drug.

Intervention

Single doses of MDMA 75mg and placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Experience with the use of MDMA (at least 5 times in the past 12 months);
2. Free from psychotropic medication;
3. Good physical health as determined by examination and laboratory analysis;
4. Absence of any major medical (except OAC), endocrine and neurological condition;
5. Normal weight, body mass index (weight/length²) between 18 and 28 kg/m²;
6. Found suitable for fMRI as confirmed by the fMRI checklist;
7. 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 alcoholic consumptions a week);
5. Hypertension (diastolic> 100; systolic> 170);
6. Current or history of psychiatric disorder;
7. Presence of metal substances/parts in the body (fMRI exclusion criterium).

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2005
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion	
Date:	25-08-2008
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	NL1355
NTR-old	NTR1416
Other	: MEC 05-090.3/pl
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A