Interactions between 3,4-methylenedioxymethamphetamine (MDMA or ’ecstasy’) and Ä9-tetrahydrocannabinol (THC or ‘marihuana’) in humans

No registrations found.

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

Summary

ID

NL-OMON27417

Source
Nationaal Trial Register

Brief title
MDMA and THC interaction

Health condition

MDMA and THC (co-) exposure

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

- Cardiovascular effects (systolic and diastolic blood pressure, heart rate) will be measured by an Acutorr plus HR/BP device regularly (with an interval of ten minutes) pre drug administration untill 4:00h after drug administration.

Another set of outcome measures consists of the following ‘state’-measurements, which will be assessed repeatedly, i.e., before MDMA administration and 0:05h, 1:00h, 1:35h, 2:30h, 4:00h and 5:00h afterwards:

- Psychomotor performance will be assessed by means of the smooth pursuit eye movements, body sway and by use of a pursuit task where the subject needs to keep the cursor in an accelerating circle (Pursuit).

- Memory and learning will be assessed by the n-back working memory task, where the subject is required to remember which dot out of a total of six lit up n times ago. The test will include the 1-, 2- and 3-back version.

- Sedation will be assessed by means of reaction time and the peak velocity of saccadic eye movements.

- Subjective effects will be assessed using the visual analog scale (VAS) by Bond and Lader and the VAS Bowdle for specific drug effects.

- Core body temperature will be assessed by means of an earthermometer (Braun pro 4000)

Secondary outcome

- Sympathetic responsiveness will be assessed by serum levels of catecholamines.

- Serotonergic responsiveness will be assessed by serum levels of cortisol and prolactin.

- Serum levels of study substances MDMA and its active metabolites as well as THC and metabolites will be assessed in the blood samples.

- Side effects will be monitored throughout.

Study description

Background summary

Ecstasy or (±) 3,4-methylenedioxymethamphetamine (MDMA) is widely used as a recreational drug. Its acute adverse effects include mental confusion, neurological-, motor effects and cardiovascular disturbances. MDMA is often used in combination with other

substances of abuse, notably alcohol and/or cannabis (active compound; THC) and is also taken at rave parties in circumstances of intense exercise and high ambient temperature. This may result in even more serious and unpredictable adverse events, but basic knowledge is lacking on these interactions. The main objective of the present experiment is to investigate to what extent acute effects of MDMA on heart rate, blood pressure, body temperature and cognitive function are influenced by co-exposure to THC (i.e., delta-9-tetrahydrocannabinol). In order to address this question, we will perform a double blind placebo controlled experiment in a group of 16 regular users of ecstasy and cannabis. The results of this exploratory study will provide details on how these substances are likely to interact to produce unwanted effects on human behaviour, physiology and biochemistry. This will lead to evidence-based information for adequate and effective prevention, and guidance for more appropriate aid in case of medical emergencies resulting from side effects.

Study objective

The main objective of this study is to investigate to what extent the acute effects of MDMA on cognitive function, prolactin and cortisol levels, body temperature, heart rate and blood pressure are influenced by co-exposure to THC.

Study design

Outcome measures consists of the following ‘state’-measurements, which will be assessed repeatedly, i.e., before MDMA administration and 0:05h, 1:00h, 1:35h, 2:30h, 4:00h and 5:00h afterwards:

Intervention

Administration of 100 mg MDMA oral and 4, 6 and 6 mg THC vaporised alone and combined

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects must be at least 18 but not older than 40 years of age.

2. Subjects must have used ecstasy on at least 8 separate occasions during the past two years.

3. Subjects must be regular users of THC; on average 2 units per week.

4. They must have good physical and mental health as determined by medical history and medical, ECG and laboratory examination.

5. Their body weight should be between 80 and 130% of the ideal bodyweight (as defined in the Metropolitan Life Insurance tables), but not less then 60kg.

6. Written informed consent.

7. Willing and able to apply an appropriate means of contraception for the duration of the treatment period.

Exclusion criteria

1. History of prescribed medication within the month prior to the start of treatment with trial medication with the exception of oral contraceptives;

2. History of OTC medication within 1 months prior to the start of treatment with trial medication with exception of occasional use of paracetamol;

3. History of opiate, LSD, amphetamine, cannabis, cocaine, alcohol, solvents or barbiturate abuse;

4. Family history of schizophrenia;

5. Medical or surgical history that in the investigator’s view may significantly affect the outcome of the trial; such as cardiovascular disorders, neurological disorders (especially epilepsy, migraine and dyslexia), psychiatric and personality disorders (especially depression,

anxiety and schizophrenia), gastro-intestinal disorders, renal or hepatic disorders, hormonal disorders (especially diabetes mellitus) and coagulation, hematological or cerebrovascular disorders, severe visual impairment;

6. Positive drug/alcohol screen before each experiment;

7. Unable to refrain from smoking during study day;

8. Febrile illness within 3 days before the first dose;

9. Clinically significant abnormal laboratory, ECG and/or EEG abnormalities; Subjects showing strong ECG and muscle artifacts, which can not be circumvented by repositioning of the EEG or reference electrodes;

10. Blood pressure at rest systolic > 170 mm Hg; diastolic > 100 mm Hg;

11. Unable or unwilling to use adequate contraception;

12. Pregnant or lactating;

13. Participation in another drug study within 6 months preceding this study;

14. Orthostatic dysregulation at the screening examination;

15. Training of cognitive tests took place more than 15 days before the start of the experimental period, i.e. day –1;

16. Inability to understand the nature and extent of the trial and the procedures required.

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):	01-06-2006
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion Date:	16-05-2008
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	NL1271
NTR-old	NTR1317
Other	: III.04.0601
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A