MDMA, Cortisol and Memory

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26979

Source
NTR

Brief title
MDMA, Cortisol and Memory

Health condition

Geheugenprestatie; neuroendocriene response (cortisol)

Sponsors and support

Primary sponsor: K.P.C. Kuypers
P.O.Box 616
6200 MD Maastricht
The Netherlands
Source(s) of monetary or material Support: NWO

Intervention

Outcome measures

Primary outcome

- Cognitive and neuro-endocrine measurements

Secondary outcome

N/A

Study description

Background summary

Ecstasy use is commonly linked with memory deficits in abstinent ecstasy users. Similar impairments are being found during ecstasy intoxication after single doses of MDMA. The concordance of memory impairments during intoxication and abstinence suggests a similar neuropharmacological mechanism underlying acute and chronic memory impairments. Cortisol has been implicated in the regulation of memory performance and might play a mediating role in MDMA induced memory impairments as well as MDMA causes an increase in cortisollevels, 1.5 h after intake. It is hypothesized that MDMA induced changes in cortisol levels underlie memory impairments in MDMA users and that the extent of this impairment is positively related to history of MDMA use. To establish the relation between (a) MDMA-induced memory impairment during abstinence and intoxication, and (b) cortisollevels, memory performance of ecstasy users will be assessed under 4 conditions. The study will be conducted according to a double blind, placebo controlled, crossover design with 4 treatment conditions and 2 groups of ecstasy users i.e. 30 novice ecstasy users and 30 heavy ecstasy users. Both groups will comprise an equal number of males and females. It will be a large sample study with 3 different main questions. (1) Role of previous MDMA use on memory function and neuroendocrine function. This will be investigated by comparing memory performance and neuroendocrine functioning of novice and heavy MDMA users during baseline (placebo) conditions. (2) Role of cortisol in MDMA-induced memory impairment. This will be investigated by comparing memory performance during four different treatment conditions (see treatments). It is expected that MDMA-induced memory impairment will be absent after combined treatment with MDMA and Metyrapone, the cortisol synthesis inhibitor, compared with placebo. (3) Role of gender in cortisol responses and memory impairment. This will be investigated by comparing memory performance and neuroendocrine function of males and females after treatment with MDMA compared with placebo.

Study objective

1. At baseline, memory performance and neuroendocrine reactions are expected to differ between novice MDMA (< 10 ecstasy exposures) users and heavy/experienced MDMA users (>100 ecstasy exposures). It is hypothesized that heavy MDMA users will be more memory-impaired and show higher cortisol levels during baseline conditions (placebo) compared to novice MDMA users.

2. After MDMA administration, memory performance is expected to be impaired in both novice and heavy user groups and cortisol responses are expected to be higher in novice users, relative to baseline, compared with heavy users.

3. After treatment with MDMA in combination with metyrapone, a cortisol synthesis inhibitor,

it is expected that MDMA-induced impairment will be absent.

4. Additionally, there appear to be gender differences with regard to cortisol responses; previously Tse and Bond (2005) have shown that gender differences in cortisol response in healthy subjects exist after a challenge with a noradrenergic compound i.e. men displayed a higher response (Tse & Bond, 2005). Differences between cortisol responses to MDMA are expected; it is hypothesized that responses are higher in females compared with males. If it is true that women display larger cortisol responses as reaction to MDMA intake, and it is known that chronic exposure to high levels of cortisol lead to changes in brain structures involved in memory, this might explain why women might be more susceptible to the neurotoxic effects of heavy ecstasy use compared with men (Reneman et al., 2001).

Study design

1. Arrival at test facilities 9:00;

2. Drug screen/ Alcohol test/ Sleep; questionnaire/ Mood Questionnaire 9:00-9:30;

3. Pre-treatment (MTP/Pla) 9:30;

4. Blood Sample 1 10:30;

5. Drug treatment (MDMA/Pla) 10:30;

6. Blood Sample 2 12:00;

7. Mood Questionnaire/ Cognitive Tests 12:00;

8. Treatment Questionnaire 13:30;

9. End of testing 13:30.

Intervention

- Placebo + MDMA (75mg)

- Metyrapone (750mg) + placebo

- Metyrapone (750mg) + MDMA (75mg)

- Placebo + Placebo

Proefpersonen zullen 4 condities (testdagen) doorlopen. Op zo een testdag zullen ze een voorbehandeling krijgen met een middel (metyrapone/placebo) die een uur later gevolgd wordt door de toediening van het tweede onderzoeksmiddel (MDMA/placebo). Anderhalf uur na inname van het tweede onderzoeksmiddel gaan proefpersonen cognitieve taken (o.a. geheugentaken) uitvoeren op een computer. Na afloop van de studie kunnen wij gaan kijken

of de prestatie (= primaire maat) op deze testen verschilt over de testcondities (behandelingen). Verder nemen we ook ieder kwartier speekselstalen. Na afloop van de studie zullen in deze stalen de niveaus van cortisol bepaald worden. We zijn geïnteresseerd in het effect van de middelen op deze levels (= 2de primaire maat).

In de studie includeren we twee groepen gezonde proefpersonen. Beide groepen zullen ervaring hebben met het gebruik van ecstasy maar de ene groep heeft weinig ervaring (lichte gebruikers) en de andere groep heeft veel ervaring (zware gebruikers). Beide groepen zullen de 4 condities doorlopen en iedere proefpersoon zal als zijn eigen controle dienen (= within subject design).

Aan de studie zal een medische keuring vooraf gaan om de gezondheidstoestand van de proefpersonen te bepalen.

Een testdag duurt van 9u ’s ochtends tot 13u30. Alle testdagen worden gescheiden van elkaar door een washout periode van minimum 7 dagen.

Contacts

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Eligibility criteria

Inclusion criteria

1. Experience with the use of MDMA (maximally 10 times in total for novice users; minimally 100 times in total for heavy users and at least once in the past 12 months for both user

groups)

2. Free from 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/height2) between 18 and 28 kg/m2

6. Written Informed Consent

Exclusion criteria

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

2. Women: Pregnancy or lactation, no use of oral contraception pill

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

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):	01-11-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL1362
NTR-old	NTR1421
CCMO	NL24590.068.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A