Can memantine prevent memory impairment induced by MDMA in humans

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37941

Source
ToetsingOnline

Brief title
MDMA and Memantine

Condition

- Other condition

Synonym
geheugenproblemen en medierend mechanisme

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MDMA, Memantine, Memory, Nicotinic receptor

Outcome measures

Primary outcome

Performance on memory tasks

Secondary outcome

Event related potentials and speech recordings

Study description

Background summary

Previous studies showed that ecstacy (MDMA) affects cognitive performance, such as memory. Many studies showed that ecstacy impairs the proces of learning new information. It is however, not known by which mechanism ecstacy causes this memoryproblem. Animal studies have shown that memantine, a drug used in the treatment of alzheimer patients, can prevent the memory problems caused by ecstacy.

Study objective

Purpose of the study is to find out if memantine in humans also has benificial effects on memory when given in combination with ecstacy. Therefore, ecstacy will be given in combination with memantine. A secondary goal is to find out the effects of ecstacy on speech. Therefore speech will be recorded.

Study design

This will be a double blind, placebo controlled, 4-way cross over design. Subjects will be pretreated with placebo or memantine. Two hours later they will be treated with placebo or MDMA. In between test days, a wash-out period of at least 2 weeks will be respected.

Intervention

Placebo + Placebo, Placebo + MDMA, Memantine + Placebo, Memantine + MDMA. Conditions will be randomised over the 4 test days.

Study burden and risks

Total amount of invested time for each subjects is about 27 hours. A medical screening will take place, including an electrocardiogram (ECG), urine and blood (8ml) analyses. Each test day will last about 6 hours. Subject have to make sure to get a good nights rest before each test day (app. 6 hours). Also they are not allowed to use cafeine or alcohol 24 hours prior to each testday. From a week before the medical screening until the end of the last test day, they can not use any drugs.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Recreational MDMA users (used at least 3 times of which at least once during the previous year, and maximally 200 times)
Age between 18 and 40 years
Free from psychotropic medication
Good physical health as determined by medical examination and laboratory analysis
Absence of any major medical, endocrine and neurological condition
Normal weight, body mass index (weight/height2) between 18.5 and 28 kg/m2
Written Informed Consent

Exclusion criteria

History of drug abuse (other than the use of MDMA) or addiction
Pregnancy or lactation
Excessive drinking (> 20 alcoholic consumptions a week)
Hypertension (diastolic> 90; systolic> 140)
Current or history of psychiatric disorder
Liver dysfunctioning
(Serious) side effects to previous MDMA use
History of cardiac dysfunctions (arrhythmia, ischemic heart disease,*)
For women: no use of a reliable contraceptive

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2011
Enrollment:	21
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ebixa
Generic name:	Memantine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	MDMA
Generic name:	MDMA

Ethics review

Approved WMO Date:	24-01-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-04-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2010-024543-33-NL
CCMO	NL35155.068.11
Other	NTR nog geen nummer toegekend