Safety profile and pharmacokinetics of 4-Fluoroamphetamine (4-FA)

Published: 01-09-2016
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The current study will evaluate the safety and pharmacokinetic profile of 4-FA.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45702

Source
ToetsingOnline

Brief title
Effects of a novel psychoactive sustance

Condition

- Other condition

Synonym
not applicable

Health condition

Veiligheid

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,The European Commision;Predicting Risk of Emerging Drugs with In silico and Clinical Toxicology (PREDICT)

Intervention

Keyword: 4-Fluoroamphetamine, Novel psychoactive substance, Pharmacokinetics, Safety profile

Outcome measures

Primary outcome

vital signs; ECG, blood pressure, heart rate, saturation, respiratory,

hematology, biochemistry and urinalysis

Secondary outcome

pharmacokinetics, cognitive performance and subjective experience

Study description

Background summary

There are lots of new psychoactive substances (NPS), such as 4-fluoroamfetamine (4-FA) available, which are widely sold under the name 'legal high' or 'research chemicals'. NPS cover a wide range of substances having pharmacological properties and effects that are similar to those of conventional drugs. In the early years, four FA was mainly added to other drugs such as ecstasy pills, and was considered adulterant or pollution. In NL is 4-FA already very popular for years, while the potential risks are not known to man. Therefore, this current study will look at the safety and pharmacological profile of 4-FA, in humans.

Study objective

The current study will evaluate the safety and pharmacokinetic profile of 4-FA.

Study design

The study is carried out in a limited number of participants (batch #1 N=6; batch #2 N=6). These subjects will receive placebo and 4-FA in an ascending dosage. Subjects will be one by one (on different days), 100 mg of 4 -FA, after which their vital signs are monitored up to 12 hours after administration. Saliva, blood,urine and earwax samples will taken at regular inervals. In addition, cognitive functioning and subjective experience will also be measured regularly. The next person will only start with the study when no substantial,

drug-related adverse events have occurred in the last person.Side effects are reported up to 72 hours after administration. An interim analysis will be carried out at the time of 3, 6, 9 and 12 people have completed this condition.

Intervention

0, 100 mg 4-FA

Study burden and risks

During the test day subjects remain 12.5 hours in the department, where their vital signs will continuously be monitored. Blood, urine, saliva and earwax samples are taken at regular intervals, and a few times the subject must perform cognitive tasks and fill out questionnaires. The subject may experience side effects that are similar or less strong than the effects of amphetamine and ecstasy / MDMA. A medical doctor will be present and can intervene in time in case of serious side effects.

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

• Previous experience with psychostimulants (<= 1 time / week) and at least one time during the previous year
• Age between 18 and 40 years
• Free from psychotropic medication
• The participant is in good health, in the opinion of the investigator, based on assessments of medical history, physical examinations, vital signs, electrocardiogram, and the results of haematology, clinical chemistry, urinalysis, serology, and other laboratory tests
• Clinical laboratory test values within the reference ranges. Borderline values may be accepted if they are, in the opinion of the investigator, clinically insignificant.
• Absence of any major medical, endocrine and neurological condition, as determined by the medical history, medical examination, electrocardiogram and laboratory analyses (haematology, clinical chemistry, urinalysis, serology)
• Normal binocular visual acuity, corrected or uncorrected
• Normal weight, body mass index (weight/height2) between 19,5 and 28 kg/m2
• Written Informed Consent

Exclusion criteria

• History of drug abuse or addiction (determined by the medical questionnaire, drug questionnaire and medical examination)
• Excessive drinking (> 20 alcoholic consumptions a week)
• Pregnancy or lactation
• Hypertension (diastolic> 90; systolic> 140)
• Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination)
• Liver dysfunction
• (Serious) side effects to previous psychostimulant use
• History of cardiac dysfunctions (arrhythmia, ischemic heart disease,*)
• Simultaneous participation in another clinical trial
• For women: not using reliable contraceptive
• Blood donor

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-01-2017
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-11-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-09-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-11-2017
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	EUCTR2016-003127-34-NL
CCMO	NL58861.068.16
Other	nog niet beschikbaar