# Effects of a novel psychoactive sustance

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27465

**Source**
Nationaal Trial Register

**Brief title**
4-FA

**Health condition**

Safety profile
Pharmacokinetics
Healty volunteers

Veiligheidsprofiel
Farmacokinetiek
Healthy volunteers

### Sponsors and support

**Primary sponsor:** Maastricht University
**Source(s) of monetary or material Support:** The European Commision, Predicting Risk of Emerging Drugs with In silico and Clinical Toxicology (PREDICT)

### Intervention

### Outcome measures

**Primary outcome**

safety profile, vital signs (body temperature, blood pressure, heart rate and respiratory rate), clinical laboratory safety (hematology, clinical chemistry and urinalysis)
and side effects

### Secondary outcome

pharmacokinetics, cognitive performance (cognitive tests), mood and subjective drug experience (questionnaires)

## Study description

### Background summary

There are probably more than a hundred novel psychoactive substances which are designed to closely mimic effects of common illicit drugs. 4-FA is a ring-substituted amphetamine with properties that are also encountered with cocaine and other amphetamine-like psychostimulants and a key feature includes the ability to increase extracellular levels of dopamine, norepinephrine and serotonin, respectively. Despite the fact that these synthetic substances have become increasingly popular and are easily available, the potential risks in humans are insufficiently known.

The present study will evaluate the safety profile and identify the side effects of 4-FA, a commonly encountered novel psychoactive substance in the EU. In addition, the pharmacokinetics of 4-FA will be determined.

Participants will take part in 3 separate test days. The sequence of drug conditions will be randomized. For safety reasons, the low dose of 4-FA will always precede the high dose of 4-FA. During each test day, they will be closely monitored for 12 hours. During this period they will remain in the laboratory under medical supervision. ECG, blood pressure, heart rate, temperature, respiration rate, SpO2 and cardiac arrhythmia will be monitored continuously by a medical supervisor, and blood samples, urine samples, oral fluid samples, will be taken regularly after administration. Cognitive performance, mood and subjective drug experience are also measured

### Study objective

To determine whether 4-FA can be safely administered in healthy volunteers in doses up to 150 mg

### Study design

Tmax

**Intervention**

Participants will receive a single dose of 100 and 150 mg of 4-FA on separate days.

# Contacts

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# Eligibility criteria

## 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

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 23-11-2016 |
| Enrollment: | 12 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 13-12-2016 |
| 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 | NL6033 |
| NTR-old | NTR6164 |
| Other | EudraCT number : 2016-003127-34 |

# Study results