Effects of a novel psychoactive sustance

Gepubliceerd: 13-12-2016 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27465

Bron
Nationaal Trial Register

Verkorte titel
4-FA

Aandoening

Safety profile
Pharmacokinetics
Healty volunteers

Veiligheidsprofiel
Farmacokinetiek
Healthy volunteers

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: The European Commision, Predicting Risk of Emerging Drugs with In silico and Clinical Toxicology (PREDICT)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

Tmax

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	23-11-2016
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-12-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6033
NTR-old	NTR6164
Ander register	EudraCT number : 2016-003127-34

Resultaten