Safety profile and pharmacokinetics of a synthetic cannabinoid (JWH-018)

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29562

Source
NTR

Health condition

JWH-018, synthetic cannabinoid, safety, pharmacokinetics

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: European Union (for study 1 and 2)

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Pharmacokinetics and pharmacodynamics

Study description

Background summary

Study 1: The study is carried out in a limited number of participants (N = 6). These subjects will be given placebo and JWH-018 in increasing doses.
Test subjects will be given one by one (on different days), 2mg JWH-018, after which their vital signs monitored up to 12 hours after administration. At regular intervals, saliva, blood and urine samples taken. In addition, cognitive function and subjective experience also measured regularly. The next person will only start with the study when there are no substantial, drug-related adverse events have occurred in the previous person. An interim analysis will be carried out when 3 and 6 persons have completed this condition.
The next part of the study, involving 3 mg JWH-018, will only start when no substantial effects have been reported with the 2mg dose. Also in this condition subjects are tested one by one, and the following subject can start only when the last day of testing was completed without substantial side effects. Side effects up to 72 hours after administration are reported. An interim analysis will be carried out when 3 people have completed this condition.

Study 2: A new group (amendment 3) of 12 subjects will be given 75µ JWH-018/kg bodyweigh and placebo. Also in this part, participants are tested one by one (on different days), and a next person will only start with the study when there are no substantial, drug-related adverse events have occurred in the previous person. Side effects up to 72 hours after administration are reported. An interim analysis will be carried out when 6 persons have completed this condition.

Study 3: A third groep (amendement 5) of 24 participants will receive 75 µg/kg JWH-018 bodyweight and placebo. When 15 minutes after administration, the subjective intoxication scale indicates that the participant does not experience a drug effect, a booster dose of 50 µg/kg JWH-018 will be administered 30 minutes after the first treatment. This will be repeated if after another 15 minutes later there is still no drug effect experienced. Participants are tested one by one (on different days), and a next person will only start with the study when there are no substantial, drug-related adverse events have occurred in the previous person. Side effects up to 72 hours after administration are reported.

Study objective

The primary objective is to determine whether JWH-018 can be safely administered in healthy volunteers in doses up to 3 mg. Therefore participants will be continuously monitored by a medical doctor and vital signs, laboratory clinical safety and side effects will be measured up until 12 hours after administration of the drug.

Secondary measures include pharmacokinetics, cognitive performance (cognitive test), mood and subjective drug experience (questionnaires).

Study design

measurements will take place up until 12 hours after administration (study 1 and 2) and up until 4h after administration (study 3)

Intervention

Study 1: 0, 2 and 3 mg JWH-018. Study 2: 75µg/kg JWH-018 and placebo. Study 3: 75µg/kg JWH-018 (+booster dose if needed) and placebo

Contacts

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Eligibility criteria

Inclusion criteria

• Used cannabis between 2 times a month and 2 times a week during the previous year

• Age between 18 and 40 years

• Free from psychotropic medication

• the subject is, in the opinion of the investigator, generally healthy based on assessment of medical history, physical examination, vital signs, electrocardiogram (ECG), and the results of the haematology, clinical chemistry, urinalysis, serology, and other laboratory tests

• a resting pulse and heart rate (as read on the ECG) □51 bpm and □100 bpm. For subjects in good physical condition, the lower limit is □45 bpm.

• a resting systolic blood pressure □91 mmHg and □140 mmHg and a resting diastolic blood

pressure □51 mmHg and □90 mmHg.

• clinical laboratory test values within the reference ranges. Borderline values may be accepted if they are, in the opinion of the investigator, clinically insignificant.

• normal binocular visual acuity, corrected or uncorrected

• 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 weight, body mass index (weight/height2) between 19,5 and 28 kg/m2

• Written Informed Consent

Exclusion criteria

• History of drug abuse (other than the use of cannabis) or addiction (determined by the medical questionnaire, drug questionnaire and medical examination)

• Experience with synthetic cannabis

• 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 cannabis use

• History of cardiac dysfunctions (arrhythmia, ischemic heart disease,…)

• Simultaneous participation in another clinical trial

• 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2015
Enrollment:	55
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-09-2016
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	NL5960
NTR-old	NTR6141
Other	Medisch Ethische Toetsingscommissie Maastricht : METC 153007

Study results