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

Published: 19-06-2015
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The current study will examine the safety and pharmacokinetic profile of JWH-018.

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

## Summary

### ID

NL-OMON46849

**Source**
ToetsingOnline

**Brief title**
Sythetic cannabinoid

### 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,Bund gegen alkohol und drogen im strassenverkehr,Universiteit Frankfurt

## Intervention

**Keyword:** JWH-018, Pharmacokinetics, Safety profile, Synthetic cannabinoid

## Outcome measures

### Primary outcome

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

hematology, biochemistry and urinalysis.

Amendement 5: cognitive functions and subjective experience

### Secondary outcome

farmacokinetics, cognitive performance and subjective experience

# Study description

### Background summary

There are many synthetic cannabinoids available, many of which are sold under the name 'legal high'. These substances with CB1 or CB2 activity, have cannabis-like effects, but often with a much stronger potency than natural cannabis. Although synthetic cannabinoids are becoming more popular the potential risk in humans is unknown. Therefore, the current study will look at the pharmacological and safety profile of JWH-018, in humans.

### Study objective

The current study will examine the safety and pharmacokinetic profile of JWH-018.

### Study design

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.

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.

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 nog 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.

**Intervention**

2 and 3 mg JWH-018
amendement 3: 75µ JWH-018/kg bodyweight
amendement 5: 75µ JWH-018/kg bodyweight and 1 or 2 booster doses of 50µ JWH-018/kg bodyweight if needed (maximal total dose 10mg JWH-018)

**Study burden and risks**

During the test day, subjects will have to stay at the research unit up to 12.5 hours, in which their vital functions will be monitored. Blood, urine and saliva samples are taken at regular intervals, and a number of times the subject will perform cognitive tasks and complete questionnaires.
The subject may experience side effects that are similar or stronger than the effects of natural cannabis. A medical doctor will be present and can intervene in time when there are serious side effects.

For part 3 of the study (amdement 4) participants will stay approximately 5

hours at the resarch site, while their bloodpressure, heart rate and side effects will be monitored. Blood, urine and saliva samples will be taken at regular intervals and at a number of times the subejct will perform cognitive tasks and complete subjective questionnaires. A medical doctor will be on stand-by.

## 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

* 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
* 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

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| Study type: | Interventional |
| Intervention model: | Crossover |
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 20-01-2016 |

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|---|---|
| Enrollment: | 55 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 19-06-2015 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 21-09-2015 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 06-10-2016 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 22-11-2016 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 22-01-2018 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 19-02-2018 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 27-09-2018 |

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| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 08-10-2018 |
| 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 |
|---|---|
| Other | NTR6141 |
| EudraCT | EUCTR2014-001803-33-NL |
| CCMO | NL52240.068.15 |