

# Safety Profile and Pharmacokinetics of 3-MMC

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53217

### Source

ToetsingOnline

### Brief title

3-MMC Safety Study

### 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:** Stichting Human Affairs

## Intervention

**Keyword:** 3-MMC, Pharmacokinetics, Safety

## Outcome measures

### Primary outcome

To determine the safety profile, vital signs (body temperature, blood pressure, heart rate), clinical laboratory safety (hematology, clinical chemistry and urinalysis) and side effects are monitored for 5.5 hours after administration of 3-MMC. Pharmacokinetics will be determined for 5.5 hours after administration: blood, urine, and oral fluid samples, will be taken at regular intervals.

### Secondary outcome

Not applicable

## Study description

### Background summary

Novel psychoactive substances (NPS) have become increasingly popular and are easily available on the recreational market, however the potential risks in humans have not been studied. 3-MMC is a novel psychoactive drug from the cathinone substitute family. 3-MMC is a monoamine transporter substrate that potently inhibits norepinephrine uptake and displays pronounced dopaminergic as well as serotonergic activity. It is closely related in structure to the more commonly known drug mephedrone (4-MMC). 3-MMC is used recreationally and known for its psychostimulant effects including empathic feelings, affection, feelings of awareness and appreciation.

### Study objective

### Primary objective

The primary objective is to determine whether 3-MMC can be safely administered in healthy volunteers in doses up to 100 mg. Participants will be monitored by a medical doctor and vital signs, laboratory safety and side effects will be measured up until 5.5 hours after administration of the drug.

### Secondary objective

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

## Study design

This exploratory study, will use a double-blind, escalating dose, placebo-controlled, within-subject design.

## Intervention

Subjects will receive placebo and single doses of 25 mg, 50 mg and 100 mg 3-MMC on separate days, following an escalating dose scheme. In the first 6 participants, the Study Safety Group (SSG) will perform an evaluation of all available safety data before allowing dosing at a higher dose level.

## Study burden and risks

Participants will take part in 4 separate test days. Subjects will be quasi randomly assigned to receive one of the following treatment orders: 0-25-50-100 mg; 25-0-50-100 mg; 25-50-0-100 mg or 25-50-100-0 mg. During each test day, subjects will be closely monitored for 5.5 hours: they will remain in the laboratory under medical supervision; ECG, blood pressure, heart rate, temperature and cardiac arrhythmia will be measured at regular intervals, and blood samples, urine samples, oral fluid samples, will be taken regularly after administration. Cognitive performance, mood and subjective drug experience will be measured at regular intervals.

## Contacts

### Public

Universiteit Maastricht

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Maastricht 6229 ER  
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### Scientific

Universiteit Maastricht

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

### **Inclusion criteria**

- Age between 18 and 40 years
- Previous experience with psychostimulants, i.e., minimum 1 time in the last 12 months
- Free from medication and dietary supplements
- The participant is, in the opinion of the investigator, generally healthy based on the assessment of medical and psychiatric history, physical examination, vital signs, electrocardiogram (ECG), and the results of the hematology, clinical chemistry, urinalysis, serology, and other laboratory tests
- Resting pulse and heart rate (as read on the ECG)  $\geq 51$  bpm and  $\leq 100$  bpm. For participants in good physical condition, the lower limit is  $\geq 45$  bpm
- Resting systolic blood pressure  $\geq 91$  mmHg and  $\leq 140$  mmHg and a resting diastolic blood pressure  $\geq 51$  mmHg and  $\leq 90$  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 (hematology, clinical chemistry, urinalysis, serology)
- Normal weight, body mass index (weight/height<sup>2</sup>) between 18,5 and 28 kg/m<sup>2</sup>
- Ability to provide written Informed Consent and comply to study requirements
- Participants must be willing to refrain from taking illicit psychoactive substances during the study
- Participants must be willing to drink only alcohol-free liquids and no coffee, black or green tea, or energy drink after midnight of the evening

before the study session, as well as during the study day

- Participants must be willing not to drive a traffic vehicle or to operate machines within 24 h after substance administration

## 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) - Tobacco smoking (>20 per day) - Current pregnancy or lactation, or pregnancy planned during study participation. Women of childbearing potential will be asked to use a proven birth control method during study participation - Hypertension (diastolic > 90; systolic > 140) - Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination) - Liver dysfunction - (Serious) side effects of previous psychostimulant use - History of cardiac dysfunctions (including arrhythmia, ischemic heart disease) - Simultaneous participation in another clinical trial - Active blood donor

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	18-10-2023
Enrollment:	16
Type:	Actual

## Ethics review

Approved WMO

Date: 24-07-2023

Application type: First submission

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
CCMO	NL84174.068.23