Safety Profile and Pharmacokinetics of 3-MMC

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Primary objectiveThe 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...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	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

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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) >= 51 bpm and <=100 bpm. For participants in good physical condition, the lower limit is >= 45 bpm
- 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 (hematology, clinical chemistry, urinalysis, serology)
- Normal weight, body mass index (weight/height2) between 18,5 and 28 kg/m2
- 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