Sub(acute) Profiling of 2C-B Versus Psilocybin

Gepubliceerd: 04-08-2020 Laatst bijgewerkt: 18-08-2022

2C-B generates distinct acute and subacute effects from Psilocybin and placebo

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

Samenvatting

ID

NL-OMON28125

Bron
NTR

Verkorte titel
PREDICT

Aandoening

N/A

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Open competition NWO grant/Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Acute dosing day performance as assessed by the digit symbol substitution task.

Toelichting onderzoek

Achtergrond van het onderzoek

2C-B is a novel psychoactive substance (NPS) which is widely used among recreational drug users, serving as a template pro-drug for new drugs of abuse and sharing phenomenological similarities with well characterised compounds such as psilocybin and MDMA.
The study intends to provide a comprehensive neuropsychopharmacological evaluation of 2C-B's acute and persisting effects versus psilocybin. The overarching goal is to develop an imaging-metabolomics machine learning algorithm, which can predict the risk-profile of NPS using point of care blood samples.

Doel van het onderzoek

2C-B generates distinct acute and subacute effects from Psilocybin and placebo

Onderzoeksopzet

Dosing day (day 1), Follow-up 1 (day 2), Follow-up 3 (day 5) x 3

Onderzoeksproduct en/of interventie

Latin square randomisation of 3 condition arms:
1. 20 mg oral 2C-B (powder, dissolved in bitter lemon drink)
2. 15 mg oral psilocybin (powder, dissolved in bitter lemon drink)
3. 200 ml bitter lemon drink (non-active control, administration solvent)
Each drug is to be administered as a solution on separate 6 hour dosing days with follow-ups the
morning after (+1 days) and 5 days later.
There will be a 2 week washout period between drug administrations.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Previous experience with at least one psychedelic substance (e.g., psilocybin, LSD, DMT, ayahuasca, psilocybe fungi ≥1 times) but not within the past three months.
2. Aged between 18 and 40 years.
3. Free from medication (any drug prescribed for a medical indication).
4. The participant 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.
5. A 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.
6. A resting systolic blood pressure ≥91 mmHg and ≤140 mmHg and a resting diastolic blood pressure ≥51 mmHg and ≤90 mmHg.
7. Clinical laboratory test values within clinical reference ranges at screening. Borderline values
may be accepted if they are, in the opinion of the investigator, clinically insignificant.
8. Normal binocular visual acuity, corrected or uncorrected.
9. 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).
10. Normal weight, body mass index.
11. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous experience of serious side effects to psychedelic drugs (anxiety or panic attacks).
2. Use of medication (other than paracetamol).

3. History of drug addiction (determined by the medical questionnaire, drug questionnaire and
medical examination).
4. Excessive alcohol consumption (>20 units a week).
5. Excessive smoking (>20 cigarettes a week).
6. Current or history of psychiatric disorder (determined by the medical questionnaire and medical examination).
7. Hypertension (diastolic >90 mmHg; systolic >140 mmHg).
8. Liver dysfunction (hepatitis, cirrhosis, cancer, biliary cholangitis, hemochromatosis, alcoholic
liver disease, etc as determined by the medical examination).
10. Renal insufficiency (as indicated by the medical examination).
11. History of cardiac dysfunctions (arrhythmia, ischemic heart disease, etc).
12. Pregnancy or lactation.
13. For women: absence of reliable contraceptive measures.
14. fMRI contraindications (pacemakers, metal implants, claustrophobia, permanent eye makeup).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-08-2021
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-08-2020
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	NL8813
Ander register	METC azm/UM : 043-3876009

Resultaten