Pharmacological Magnetic Resonance Spectroscopy

Gepubliceerd: 22-10-2020 Laatst bijgewerkt: 15-05-2024

We hypothesize that added neurometabolite measurements can contribute to the interpretation of the ketamine phMRI response.

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

Samenvatting

ID

NL-OMON29216

Bron
Nationaal Trial Register

Verkorte titel
phMRS

Aandoening

NA

Ondersteuning

Primaire sponsor: Amsterdam University Medical Center, location AMC
Overige ondersteuning: NWO Veni

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in levels of GABA, glutamate, and lactate in PFC; phMRI signal in PFC.

Toelichting onderzoek

Achtergrond van het onderzoek

Pharmacological magnetic resonance imaging (phMRI), which measures the blood flow response to drug-induced neuronal activation, is a promising technique to non-invasively assess the brain's response to psychotropic medication. However, phMRI measures are blood flow based and therefore often contaminated by (systemic) cardiovascular effects frequently induced by psychotropic medication. Magnetic resonance spectroscopy has been suggested as a technique to more directly assess drug-induced neuronal activity and therefore allow a more complete characterization of the brain response to psychotropic medication. We hypothesise that concurrent measurements of the hemodynamic response and glutamate/GABA levels (with MRS) during drug administration will provide the much-needed information to interpret the underlying neuronal contribution to the phMRI signal. The aim of the proposed study is to provide evidence for this hypothesis.

Doel van het onderzoek

We hypothesize that added neurometabolite measurements can contribute to the interpretation of the ketamine phMRI response.

Onderzoeksopzet

screening and 3 visits, at least 1 week apart

Onderzoeksproduct en/of interventie

Subjects will receive intravenous 0.11 mg/kg S-ketamine, 0.22 mg/kg S-ketamine or placebo during a phMRI/phMRS scan on different test sessions in randomized order.

Contactpersonen

Publiek

Amsterdam University Medical Center

Anouk Schrantee

+31205668327

Wetenschappelijk

Amsterdam University Medical Center
Anouk Schrantee

+31205668327

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

● Healthy volunteers between 18 and 55 years old;
● BMI between 18.5 and 25;
● Male or female;
● If female: using oral contraceptives and not in hormone-free week during scanning

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

● (History of) psychiatric treatment, for which prescription medication is used;
● First-degree relative with (history of) schizophrenia or major depression;
● (History) of neurological disorders (including stroke, convulsion, epilepsy) as well as concussion
with loss of consciousness
● Contraindications for S-ketamine (e.g. allergy for S-ketamine, or one of the inactive ingredients
of this product, high BP (RRsystolic > 180 mmHg or diastolic >100 mmHg), use of xantiderivatives
or methylergometrine); use of substances that interact with S-ketamine (e.g. grapefruit juice, antifungal medication)
● Contraindications for 7T MRI (e.g. claustrophobia, osteosynthetic material, pacemaker, artificial
cardiac valves);
● (History of) drug (opiate, LSD, (meth)amphetamine, cocaine, solvents, cannabis, or barbiturate)
or alcohol dependence;
● Used psychotropic medication, or recreational drugs over a period of 1 week prior to each

test
session;
● Used alcohol within the last 24 hours prior to each test session.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-10-2020
Aantal proefpersonen:	30
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:	22-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49551
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8994
CCMO	NL74447.018.20
OMON	NL-OMON49551

Resultaten