Pharmacological Magnetic Resonance Spectroscopy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29216

Source
Nationaal Trial Register

Brief title
phMRS

Health condition

NA

Sponsors and support

Primary sponsor: Amsterdam University Medical Center, location AMC
Source(s) of monetary or material Support: NWO Veni

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

● Functional connectivity

● Score on a Visual Analog Scale (VAS), to quantifies subjective measure of the sedative effect
of S-ketamine
● Clinician Administered Dissociative States Scale (CADSS) to monitor changes in dissociative state due to placebo or ketamine administration.
● Blood samples will be obtained at several time points to assess the plasma concentration of S-ketamine and its active metabolite S-norketamine.

Study description

Background summary

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.

Study objective

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

Study design

screening and 3 visits, at least 1 week apart

Intervention

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.

Contacts

Public
Amsterdam University Medical Center
Anouk Schrantee

+31205668327
Scientific
Amsterdam University Medical Center
Anouk Schrantee

+31205668327

Eligibility criteria

Inclusion criteria

● 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

Exclusion criteria

● (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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-10-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49551
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results