Can the sGC stimulator Adempas (riociguat) improve cognitive functioning in healthy volunteers?

No registrations found.

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

Summary

ID

NL-OMON22467

Source
Nationaal Trial Register

Brief title
sGC stimulator and cognitive improvement

Health condition

Memory
Attention

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: Maastricht University

Intervention

Outcome measures

Primary outcome

The primary endpoint is the behavioral scores on a memory paradigm, namely a verbal learning task.

Secondary outcome

Secondary endpoints are performance on the visual N-back test, a spatial memory task (SMT), the attention network test (ANT) and a simple and choice reaction task, the scores on the POMS and complaints questionnaire.

Study description

Intervention

Participants will participate on 6 separate test days and will be administered either biperiden, riociguat, a combination, or a placebo. The order of treatment will be counterbalanced.

Contacts

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Eligibility criteria

Inclusion criteria

• In the opinion of the investigator, the participant is capable of understanding and complying with protocol requirements.

• The participant is aged 18 to 40 years, inclusive, at the time of informed consent.

• The participant has a body mass index of 18.5-30 kg/m2, inclusive, at medical screening.

• The volunteer is healthy, i.e. absence of all exclusion criteria and has normal static binocular acuity.

• The participant signs and dates a written informed consent form before the start of the experiments.

Exclusion criteria

• The subject has uncontrolled, clinically significant neurologic, cardiovascular, pulmonary, hepatic, renal, metabolic, gastrointestinal, or endocrine disease or other abnormality which may impact the ability of the subject to participate or potentially confound the study results.

• The volunteer has uncontrolled existing major psychiatric symptoms.

• The subject has uncontrolled hypo- or hypertension.

• The participant has known hypersensitivity to any component of the formulation of riociguat or biperiden or related compounds.

• The subject has a history of drug abuse (defined as any illicit drug use) or a history of alcohol abuse within 1 year prior to the first visit or is unwilling to agree to abstain from alcohol from 24 hours prior to each test day and/or drugs throughout the study.

• The participant has any sensory or motor deficits which could reasonably be expected to affect test performance.

• Other exclusion criteria are smoking, excessive drinking (>20 glasses of alcohol containing beverages a week), pregnancy or lactation, use of medication other than oral contraceptives.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Control: Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2016
Application type:	First submission

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
NTR-new	NL5563
NTR-old	NTR5684

Register	ID
Other	METC AZM/UM : 153012

Study results