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

Gepubliceerd: 11-02-2016 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON22467

Bron
NTR

Verkorte titel
sGC stimulator and cognitive improvement

Aandoening

Memory
Attention

Ondersteuning

Primaire sponsor: Maastricht University
Overige ondersteuning: Maastricht University

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd

Controle: Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-02-2016
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2016
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	NL5563
NTR-old	NTR5684
Ander register	METC AZM/UM : 153012

Resultaten