Examining the pharmacokinetic and pharmacodynamic profile of biperiden

No registrations found.

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

Summary

ID

NL-OMON24672

Source
NTR

Brief title
PK/PD biperiden

Health condition

geheugen/ memory

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The main endpoints for the cognitive tasks are the behavioral score on the immediate and delayed recall of the VLT. This includes the number of words recalled immediately and after a 20 minute delay.

Secondary outcome

Secondary, to establish the pharmacokinetic and pharmacodynamics profile of biperiden the primary endpoints will be the blood serum values and physiological measures (body temperature, blood pressure, heart rate and pupil size). Furthermore the behavioral outcomes of the n-back and simple and choice reaction tasks will be used for analysis, as well as the scores on the B&L and complaints questionnaire. Next to this, the event-related potentials during the behavioural tasks will be analysed. Another important measure is the brain response to the novelty oddball task, which will give an indication of the role of acetylcholine in novelty processing.

Study description

Intervention

Subjects will participate in 3 treatment conditions: i.e. placebo, biperiden 2 mg and 4 mg. All medications will be administered orally. Order of treatments will be balanced over three test sessions, which will be separated by a washout period of at least 7 days.

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

• The participant is aged 18 to 35 years, inclusive, at the time of informed consent.

• The volunteer is healthy, i.e. absence of all exclusion criteria and had normal or corrected to normal static binocular acuity with or without correction.

• 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 participant has known hypersensitivity to any component of the formulation 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
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2017
Enrollment:	27
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-02-2017
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	NL6094

Register	ID
NTR-old	NTR6241
Other	METC azM/UM : 163037

Study results