Biperiden challenge study

No registrations found.

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

Summary

ID

NL-OMON26607

Source
Nationaal Trial Register

Health condition

Healthy volunteers, challenge model, biperiden, Alzheimer's disease

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

 Saccadic eye movement

 Smooth pursuit

 Pupillometry

 Body Sway

 N-Back task

 Adaptive tracking test

 Visual analogue scales (VAS) for alertness, mood, calmness and nausea

 Tapping test

 Visual verbal learning test (VVLT)

 EEG (resting state, ERP: MMN)

Pharmacokinetics

Secondary outcome

-

Study description

Background summary

Administration of biperiden has been shown to lead to impairments in episodic and working memory. In this study we aim to validate biperiden as a cognitive challenge model to be used for proof-of-pharmacology of selective muscarinic M1 agonists. We will investigate two dose levels of biperiden in healthy elderly subjects, and we will perform PD testing on mulitple time points using a comprehensive computerised central nervous system (CNS) test battery (NeuroCart) to explore the duration of the biperiden effect and to observe when the maximum PD effect is reached

Study objective

Biperiden deteriorate the cognition that biperiden will be used for a challenge model.

Study design

PD: pre-dose, 1, 2.5, 4, 7, 22 hours post dose

PK: pre-dose, 0.5, 1, 1.5, 2, 2.5, 4, 7, 10, 22 hours post dose

Intervention

Safety (AEs, lab, ECG, vital signs)

Saccadic eye movement

Smooth pursuit

Pupillometry

Body Sway

N-Back task

Adaptive tracking test

Visual analogue scales (VAS) for alertness, mood, calmness and nausea

Tapping test

Visual verbal learning test (VVLT)

EEG (resting state, ERP: MMN)

Contacts

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Eligibility criteria

Inclusion criteria

1. Elderly male or female subjects aged between 65 and 80 (inclusive) years old;

2. Healthy subjects as defined by the absence of evidence of any clinically relevant active or chronic disease following detailed medical and surgical history review and a complete physical examination including vital signs, 12-lead ECG, haematology, blood chemistry, and urinalysis;

3. BMI between 18 and 34 kg/m2, inclusive;

4. Female subjects should be postmenopausal. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause. A high follicle stimulating hormone (FSH) level at screening (>40 IU/L or mIU/mL) in the postmenopausal range may be used to confirm a postmenopausal state in women.

5. Able to understand the commitments of the study and to communicate effectively with the investigator and site staff;

6. Absence of cognitive impairment evident by a score of 28 or higher on the Mini Mental State Examination (MMSE);

7. Able to participate and willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

1. Clinically relevant history of abnormal physical or mental health interfering with the study as determined from the medical history review and the physical examinations obtained during the screening visit and/or at the start of the first study day for each period as judged by the investigator (including (but not limited to), neurological, psychiatric, endocrine, cardiovascular (including recent myocardial infarction), respiratory, gastrointestinal, hepatic, renal disorder or presence of narrow-angle glaucoma).

2. History or clinical evidence of any disease and/or existence of any surgical or medical condition which might interfere with the absorption, distribution, metabolism or excretion of the study drugs.

3. Any disease associated with cognitive impairment, including but not limited to schizophrenia and dementia.

4. History of severe allergies, or history of an anaphylactic reaction to prescription or non-prescription drugs or food.

5. History of hypersensitivity to biperiden or to the excipients used in the biperiden formulation (Maize starch, Lactose monohydrate, Microcrystalline cellulose, Calcium hydrogen phosphate, Copovidone, Talc, Magnesium stearate, Potato starch)

6. Positive test for Hepatitis B surface antigen (HBsAg), Hepatitis C antibody (HCV Ab), or human immunodeficiency virus antibody (HIV Ab) at screening.

7. Positive urine drug screen (UDS), or alcohol test at screening and/or upon admission to the Clinical Research Unit (CRU).

8. Presence or history (within 3 months of screening) of alcohol abuse confirmed by medical history, or daily alcohol consumption exceeding 2 standard drinks per day on average for females or exceeding 3 standard drinks per day on average for males (1 standard drink = 10 grams of alcohol), and the inability to refrain from alcohol during the visits until discharge from the CRU (alcohol consumption will be prohibited during study confinement).

9. Use of tobacco and/or nicotine-containing products within 90 days of dosing and throughout the study until follow-up.

10. Excessive caffeine consumption, defined as >800 mg per day from 7 days prior to the first dose of the study drug until 24 hours prior to dosing. Subjects will abstain from caffeine-containing products for 24 hours prior each dosing and whilst in the study unit until discharge from the study unit. At other times throughout the study, subjects should not consume more than 800 mg caffeine per day. Caffeine quantities defined as: one cup of coffee contains 100 mg of caffeine; one cup of tea, or one glass of cola, or potion of chocolate (dark:100 g, milk 200 g) contains approximately 40 mg of caffeine; one bottle of Red Bull contains approximately 80 mg of caffeine.

11. Any other concurrent disease or condition that could interfere with, or for which the concomitant treatment might interfere with, the conduct of the study, or that would, in the opinion of the Investigator, pose an unacceptable risk to the subject in this study.

12. Participation in an investigational drug trial in the 3 months prior to administration of the initial dose of study drug or more than 4 times per year.

13. Donation or loss of blood of more than 500 mL within 3 months (males) or 4 months (females) prior to screening.

14. Use of concomitant medications within 14 days prior to study drug administration or within 5 half-live (whichever is longer).

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):	15-08-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-06-2018
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	NL7146
NTR-old	NTR7344
Other	NL64171.056.17 : chdr1653

Study results