A pilot study exploring the reproducibility and suitability for multi-center clinical trials of fMRI bold signal during a monetary incentive delay task and arterial spin labeling with and without prior administration of Risperidone

Published: 20-02-2018
Last updated: 12-04-2024

The purpose of this study is to explore if the (f)MRI- and behavioral assessment are reproducible and suitable for drug studies performed at more than one medical center or clinic.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46683

Source
ToetsingOnline

Brief title
Site Evaluation Pilot Study

Condition

- Other condition

Synonym
Specific imaging methods

Health condition

n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Millennium Pharmaceuticals, Inc. A Takeda Oncology Company
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: MRI, Pilot, Risperidon

Outcome measures

Primary outcome

fMRI

Secondary outcome

n.v.t.

Study description

Background summary

The sponsor is interested to increase the number of clinical sites capable of supporting clinical magnetic resonance imaging (MRI) trials for the development of drugs acting on the function of the brains (i.e. the Central Nervous System [CNS]).

Most clinical trials are conducted at several clinical research centers. The advantages of multicenter studies are a larger number of participants, different geographic locations, and different population groups. However, a very limited number of clinic sites can support MRI studies. UMCG Neuroimaging Center and PRA have experience with the conduct of MRI in combination with behavioral assessments to study the effect of medical interventions.

The sponsor is also interested in exploring the reproducibility of the specific imaging methods discussed here which are considered of interest in the context

of The Sponsor*s drug development pipeline across different sites and scanner platforms.

The study will be performed in up to 5 volunteers who will participate in 2 visits during which MRI and behavioral assessment will be performed, once with and once without prior administration of risperidone.

Study objective

The purpose of this study is to explore if the (f)MRI- and behavioral assessment are reproducible and suitable for drug studies performed at more than one medical center or clinic.

Study design

The actual study will consist of 2 visits during which the volunteer will stay at the PRA research center in Groningen [clinical site UMCG] for 2 days (1 night). There is a period of 5 days (6 nights) between the 2 visits the volunteer will stay at home.

The MRI scans and assessments will be at Day 1 and Day 8. The volunteer is expected at the research center at 14:00 h in the afternoon prior to the day of the MRI scans and assessments. The volunteer will leave the research center in the afternoon after completion of all assessments on Day 1 and Day 8, respectively.
This will be followed by 7-14 days during which the volunteer will be called at home once. The volunteer will then be asked how he feels and whether he uses any medication.

This study is an open-label, 2 imaging sessions study in up to 5 healthy male volunteers, with and without prior administration of risperidone.

The volunteer will be assigned to 2 treatments, one without risperidone (Treatment A) and one with risperidone (Treatment B; a single dose of 2 mg of risperidone). Prior to the MRI scan on Day 1, volunteers will be assigned to receive first Treatment A followed by Treatment B (A/B), or first Treatment B followed by treatment A (B/A).

Risperidone will be given as an oral tablet with 240 ml of (tap) water 2 hours before fMRI scanning and should not be chewed.

Group Day Treatment How Often
1 1 A: no risperidone n/a
8 B: 2 mg risperidone 2 hours before MRI once
2 1 B: 2 mg risperidone 2 hours before MRI once
8 A: no risperidone n/a

Study burden and risks

Risperidone may cause side effects.

The most common adverse reactions in clinical studies were somnolence, appetite increased, fatigue, common cold (rhinitis), upper respiratory tract infection, vomiting, coughing, urinary incontinence, saliva increased, constipation, fever, abdominal pain, nausea, dry mouth, rash, restlessness and compelling need to be in constant motion (akathisia), Parkinsonism, neurological movement disorder (dystonia), anxiety, dizziness, unintentional muscle movement (tremor), restlessness and compelling need to be in constant motion (akathisia), and feeling of unusual fullness following meals/nausea/heartburn (dyspepsia).

Side effects may affect the driving skill. Hence the volunteer is not allowed to drive home after discharge on treatment Day 1 and 8.

Drawing blood may be painful or cause some bruising. We will draw a small volume of blood during the pre-study screening.

To measure the heart rate, electrodes (small, plastic patches) will be pasted at specific locations on the chest and abdomen. Use of these electrodes can cause skin irritation (rash and itching). An ECG will be made during the pre-study screening.

The MRI/fMRI scans are not associated with any radioactivity and there are no adverse effects to be expected.

Contacts

Public
Millennium Pharmaceuticals, Inc. A Takeda Oncology Company

Massachusetts Avenue 350
Cambridge MA 02139
US
Scientific
Millennium Pharmaceuticals, Inc. A Takeda Oncology Company

Massachusetts Avenue 350
Cambridge MA 02139
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- healthy male subjects
- 18 to 45 yrs, inclusive, at screening
- BMI: 18.0 to 30.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	20-02-2018
Enrollment:	5
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Risperidone
Generic name:	N/A

Ethics review

Approved WMO Date:	20-02-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2018-000379-34-NL
CCMO	NL64930.056.18