NON-DRUG, SINGLE SITE, FMRI AND BEHAVIOR ASSESSMENT OPTIMIZATION STUDY IN HEALTHY VOLUNTEERS

Published: 26-08-2015
Last updated: 20-04-2024

In this study, behavioral tests will be performed during the fMRI scan to investigate the brain*s response to these tests. Behavioral tests will also be performed outside the scanner. The results of the study will be used for optimizing the fMRI…

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

Summary

ID

NL-OMON42589

Source
ToetsingOnline

Brief title
fMRI optimalization study

Condition

- Other condition

Synonym
n/a

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: F. Hoffmann-La Roche Ltd.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: fMRI

Outcome measures

Primary outcome

fMRI optimalisation

Secondary outcome

n/a

Study description

Background summary

One of the techniques used in this study, functional magnetic resonance imaging (fMRI), uses strong magnetic fields to measure brain activity based on changes in blood flow in the brain. This technique relies on the fact that cerebral blood flow and neuronal activation are coupled. When an area of the brain is in use, blood flow to that region increases.

Study objective

In this study, behavioral tests will be performed during the fMRI scan to investigate the brain*s response to these tests. Behavioral tests will also be performed outside the scanner.

The results of the study will be used for optimizing the fMRI technique and the application of behavioral tests for use in future studies on drugs that may have an effect on brain activity.

Study design

The study will be performed in 2 parts, Parts A and B. Part A will be performed in 5 volunteers who will participate in 1 visit with fMRI tasks and behavioral tasks based on which the fMRI settings may be optimized and behavioral

assessments may be adapted for use in Part B. Part B will be performed in 30 volunteers who will participate in 2 visits during which fMRI tasks and behavioral tasks will be performed. It will determine whether the results of the first visit are reproducible in the second visit.

Study burden and risks

With regard to the fMRI, no radioactivity will be applied and there are no adverse effects to be expected.

Contacts

Public
F. Hoffmann-La Roche Ltd.

6 Falcon Way, Shire Park
Welwyn Garden City AL7 1TW
GB
Scientific
F. Hoffmann-La Roche Ltd.

6 Falcon Way, Shire Park
Welwyn Garden City AL7 1TW
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* willing to participate in this study
* healthy male or female
* age between 18 and 45 years of age, inclusive
* BMI between 18 and 30 kilograms/meter2, inclusive, body weight between 50 and 100 kilogram, inclusive
* non-smokers and smokers (smoke less than 11 cigarettes per day (or comparable amount of cigars or pipe)

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2015
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	26-08-2015
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
CCMO	NL54292.056.15