[18F]-FHBG for PET imaging of herpes viruses: a control study with healthy volunteers

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The primary objective is to determine the metabolic rate of [18F]-FHBG in the brain of healthy volunteers, for comparison with the metabolic rate that was found in schizophrenic patients in the previous study.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON35582

Source
ToetsingOnline

Brief title
[18F]-FHBG PET with healthy volunteers

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychiatric disorder, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stanley Medical Research Foundation

Intervention

Keyword: [18F]-FHBG, Positron emission tomography

Outcome measures

Primary outcome

The main study parameter is the metabolic rate of [18F]-FHBG in the brain.

Secondary outcome

Secondary study parameters are the results of the PANSS, 15-word test, CPT and

the antibodies against herpes viruses.

Study description

Background summary

In a previous pilot study on the role of herpes viruses in schizophrenia it was found that severely affected schizophrenic patients (based on severity of psychosis and memory disorder), had a significantly higher metabolic rate of the PET tracer [18F]-FHBG in the temporal lobe, when compared to mildly affected patients. The higher metabolic rate of [18F]-FHBG suggests the presence of active herpes viruses. In order to draw the right conclusion on the presence of active herpes viruses in the temporal lobe of schizophrenic patients, it is of importance to compare the metabolic rate of [18F]-FHBG in patients, to the metabolic rate in healthy volunteers.

Study objective

The primary objective is to determine the metabolic rate of [18F]-FHBG in the brain of healthy volunteers, for comparison with the metabolic rate that was found in schizophrenic patients in the previous study.

Study design

This study in healthy volunteers is a pilot study that will performed in addition to the previous pilot study in schizophrenic patients that was started in 2005. The study design in the present study will be equal to the study design in the previous study, to allow for comparison between the healthy volunteers and the schizophrenic patients.
Healthy volunteers will be recruited via advertisement in public buildings and

local newspapers. Interested healthy volunteers will receive both oral and written information about the study and will have two weeks time for reflection to decide whether or not to participate in the study. Healthy volunteers that would like to participate in the study are asked to sign the written informed consent. To determine whether the inclusion and exclusion criteria are met, the healthy volunteer has to fill in a questionnaire. When the healthy volunteer meets the inclusion and exclusion criteria, he/she is scheduled for the PANSS-interview, and the attention and memory tests. Within two weeks after the PANSS-interview and the tests, the [18F]-FHBG PET scan will be performed. Prior to the PET scan, blood will be collected for determination of antibodies against herpes viruses.

Study burden and risks

The healthy volunteers are exposed to radioactivity with minor to moderate risk, according to the International Commission on Radiological Protection (ICRP62). Healthy volunteers do not benefit from the study, but their participation may lead towards a better understanding on the role of herpes viruses in schizophrenia (i.e. the etiology of schizophrenia) and may lead towards improved treatment strategies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Age above 18
-Written informed consent for participation

Exclusion criteria

-Pregnancy, or presumption of pregnancy
-The use of anticoagulants or having coagulation disorder
-Use of any investigational drug
-Use of somatic medication which may affect the immune system
-Current or recent (<1 year) alcohol or substance abuse
-Current psychiatric disorder or a first degree family member with a major psychiatric disorder
-Current systemic disease
-Current infection with a herpes virus
-Major metabolic disease
-Somatic, organic or neurological disorder
-Participation in a scientific research study (<1 year) involving radiation

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	25-06-2012
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37503.042.11