Probing microglial activation in psychosis.

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To assess microglial activation in first episode patients with psychotic symptoms and first episode medication naïve patients with psychotic symptoms compared to healthy controls using the positron emission tomography (PET) tracer [11C]-R-PK11195.

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

Summary

ID

NL-OMON39140

Source
ToetsingOnline

Brief title
Probing microglial activation in psychosis.

Condition

- Schizophrenia and other psychotic disorders

Synonym
'schizophrenia' 'psychosis'

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: nog aan te vragen fondsen; onderzoek geprefinancieeerd uit eigen middelen

Intervention

Keyword: microglia, positron emission tomography, psychosis, schizophrenia

Outcome measures

Primary outcome

The primary outcome is the difference in [11C]-R-PK11195 binding potential (BPND) in various brain regions between subjects with psychosis and healthy controls.

Secondary outcome

The secondary outcome is the relation between microglial activation and other markers for neuronal damage and inflammation. This includes grey matter loss, white matter damage and loss of functional connectivity between brain regions, as well as inflammatory cytokine concentrations in serum.

Study description

Background summary

The pathophysiology of schizophrenia and psychosis is currently unclear. Growing evidence indicates that neurodegeneration and neuroinflammation is present in patients with schizophrenia. Microglia activation can be used as an indirect marker to assess neuronal degeneration and inflammation in schizophrenia. Previous studies found microglial activation in total gray matter in schizophrenia patients.

Study objective

To assess microglial activation in first episode patients with psychotic symptoms and first episode medication naïve patients with psychotic symptoms compared to healthy controls using the positron emission tomography (PET) tracer [11C]-R-PK11195.

Study design

This is an open study. All subjects will receive a dose of max. 370 MBq [11C]-R-PK11195.

Study burden and risks

In total there will be three sessions: a screening session, a visit to the Department of Nuclear Medicine & PET research of the VU Medical Center (VUmc), and a magnetic resonance imaging (MRI) scan in the University Medical Center Utrecht (UMCU). During the screening session questionnaires has to be filled in and interviews will be held, such as the Comprehensive Assessment of Symptoms and History (CASH), and standard laboratory tests (2 blood samples, max. 5 ml each; urine drug test) are performed. During the second visit a magnetic resonance imaging (MRI) scan will be acquired. Minimal risks are associated with MRI acquisition.
At the third visit a positron emission tomography (PET) scan will be acquired. The risks associated with PET scanning are limited, but the subjects will receive tracer doses of radiation, which is estimated at max. 1.9 milli-Sievert (mSv). Before PET tracer administration a small sample of blood (max. 5 ml) will be withdrawn to assess the immunologic concentrations in serum. No immediate benefits are to be expected from participation in this study for the subjects. However, an indirect effect in the future is plausible for subjects with schizophrenia and psychosis, since more knowledge about schizophrenia may lead to early detection of the disease or improvement in therapy.

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

-Men and women
-Mini Mental State score >27
-Written informed consent of the subject;Specific for patients with psychotic symptoms:
- Presence of schizophrenic and psychotic symptoms according to DSM-IV criteria using the Comprehensive Assessment of Symptoms and History interview (CASH) (N.B. Official DSM-IV diagnosis can be performed six months after onset of symptoms.)

Exclusion criteria

Healthy controls:
-History of psychiatric or neurological illness based (DSM-IV criteria)
-First-degree relatives with a family history of schizophrenia or schizophrenia spectrum disorders
-Any neurological disorder
-(History of) Alcohol and/or drug abuse (DSM-IV criteria)
-Any clinical significant abnormality of any clinical laboratory test, including drug screening (but positive cannabis test is allowed for patients)
-Any condition that may interfere with MRI scanning, e.g. metal objects in or around the body or claustrophobia
-Pregnancy;Specific for medicated patients with psychotic symptoms:
- Any neurological disorder;Specific for first episode medication-naive patients with psychotic symptoms:
- Use of antipsychotics
- Treating physician does not support a delay of medication for the patient (from a clinical perspective)
- Risk that the patient causes serious harm to oneself or others
- Clinical Global Impressions Severity (CGI-S) score 5 or higher
- Psychotic symptoms are too severe to participate (based on CGI-S score and clinical view of treating physician)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-09-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-09-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-03-2013
Application type:	Amendment

Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL34092.041.10