The effect of biological and environmental factors on the course of cognition in First Episode Schizophrenia patients and High Risk Subjects

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1. How is the development of cognition over the time period of one year, assessed by the MATRICS cognitive test battery, in a study population of First Episode Schizophrenia patients and Ultra High Risk subjects?2. What is the potential predictive...

Ethical review	Approved WMO
Status	Pending
Health condition type	Disturbances in thinking and perception
Study type	Observational invasive

Summary

ID

NL-OMON31164

Source
ToetsingOnline

Brief title
The Effect of biology and environment on cognition in schizophrenia

Condition

- Disturbances in thinking and perception

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,Top Instituut Pharma, onderzoeksinstituut voor geneesmiddelenonderzoek,Top Instituut Pharma;onderzoeksinstituut voor geneesmiddelenonderzoek

Intervention

Keyword: cognition, genetics, MRI, schizophrenia

Outcome measures

Primary outcome

The most important study parameters are the results of the cognitive test battery MATRICS with an interval of 1 year. Using the MATRICS the course of cognitive functioning can be assessed and in the High Risk group, the persons that make the transition to psychosis can be tested for changes in cognitive functioning

Secondary outcome

The secundary study parameters are the biological data (MRI, genetics), behavioral data (Pre Pulse Inhibition) and environmental data (cannabis use) that are linked to the cognitive data. In this manner potential predisposing factors for cognitive functioning can be identified.

Study description

Background summary

Cognitive deficits (problems with thinking abilities, such as learning, memory and attention) are core features of schizophrenia and may be major determinants of social and occupational functioning. Thus far, there has been a lack of effective treatments for these deficits. TURNS is a NIMH-funded contract to evaluate new compounds for the treatment of cognitive impairment in schizophrenia. TURNS is the 2nd part of an initiative (followed by a study called MATRICS * Measurement and Treatment Research to Improve Cognition in Schizophrenia) from the NIMH and the FDA to reach a consensus on standards of

measurement for cognition and clinical trials design. In the MATRICS study, a standardized cognitive test battery was developed for use in the TURNS study. In the proposed TIP University of Amsterdam project the intention is to assess cognitive and functional deficits in four groups: subjects running a High Risk of developing schizophrenia-like psychoses (HR subjects) and First-Episode patients with schizophrenia-like psychoses who are either cannabis users or non-users, as well as the potential predictive validity of genetic and other biomarkers.

Study objective

1. How is the development of cognition over the time period of one year, assessed by the MATRICS cognitive test battery, in a study population of First Episode Schizophrenia patients and Ultra High Risk subjects?
2. What is the potential predictive value of biomarkers (genetics, structural MRI), behavioral (Pre Pulse Inhibiting) and environmental factors (cannabis use) for cognitive functioning after one year

Study design

This is a case control study with two patient populations and a control group. Participants will be requested to come to the psychiatry ward of the AMC for 1 day at T0 and half a day at T2
The participants will be subjected to the following tests:
T=O:
- Intake: psychological tests as screening instruments for psychopathology (PANSS, CASH), somatical history, basic physical examination, time: 1.5 hours
- MATRICS test battery, time: 1.5 hours
- MRI scan, time: 30 minutes
- Pre Pulse Inhibiting research (PPI), time: 15 minutes
- Venal punction 20 ml and testing for cannabis in the urine, time: 20 minutes

T=1:
- MATRICS test battery, time 1.5 hours
- PANSS, time 45 minutes

Timetable:
The study will be performed between august 2007 and july 2010
aug* 07 - dec *07: - translating MATRICS test battery and performing PILOT study, recruitment of subjects
jan - juli *08: - T0 measurements in patients and healthy controls
aug - dec *08: - training in the molecular genetic laboratory and performing genetic research
juli *09: - T1 measurements in patients and healthy controls
aug *09 - juli*10 - analysing of data

Study burden and risks

Participating in this study has minimal risks for the participants. The risks are those related to a venal punction (haematoma or, very rare, vasovagal collaps) and the making of an MRI scan without the use of any contrast. All participants will we screened for the presence of metals in the body, pregnancy and potential fears (claustrofobia) or bad experiences with MRI investigation. There is no direct benefit in participating for the patients, but participating will contribute to more knowledge about schizophrenia and High Risk subjects. There is no group relatedness, all participants receive the same treatment.

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

The First Episode Schizophrenia patients will have to meet the DSM-IV criteria for schizophrenia and this diagnosis should not have been assessed in the past.
The Ultra High Risk patients will be assessed using the Structured Interview of Prodromal Symptoms (SIPS) and

Exclusion criteria

pregnancy,
metals in the body contraindicated in MRI inverstigation

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:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL19591.018.07