Activating the frontal brain in schizophrenia: comparison of aripiprazole versus resperidone using functional magnetic resonance imaging

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This study looks if the third generation antipsychotic aripiprazole can improve activity of the prefrontal cortex and cognitive and social function, when compared to the second generation antipsychotic risperidone.

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

Summary

ID

NL-OMON31229

Source
ToetsingOnline

Brief title
MRI study on the effect of Abilify versus Risperdal

Condition

- Schizophrenia and other psychotic disorders

Synonym
chronic psychosis, Schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Europian Young Investigators Award

Intervention

Keyword: aripiprazole, fMRI, frontal cortex, risperidone

Outcome measures

Primary outcome

Difference in brain activity of the prefrontal cortex between groups with

different medication. Besides accuraty and reactiontimes during task

performance and severeness of positive and negative symptoms.

Secondary outcome

nvt

Study description

Background summary

Schizophrenia is characterized by a widespread cognitive disfunction, affecting the domains of memory, learning, attention and executive functioning. Besides, disabilities in social functioning excist, one of the main characteristics of schizophrenia. These problems are possibly caused by disminished activity of the prefrontal cortex. The third generation antipsychotic Abilify (aripipralole) can restore improve the activity of the prefrontal cortrex. This could cause a decrease in negative symptoms and improve social cognition. Risperdal (risperidone) has another mode of action, in which dopamine is blocked in the whole brain. Therefore the expectations are that activity of the prefrontal cortex will not increase substantially when Risperdal is prescribed, in contrast to Abilify that will activate the prefrontal cortex.

Study objective

This study looks if the third generation antipsychotic aripiprazole can improve activity of the prefrontal cortex and cognitive and social function, when compared to the second generation antipsychotic risperidone.

Study design

24 patients suffering from schizophrenia will be randomly assigned to Abilify (aripiprazole) or Risperdal (risperidone), only when no clear preference excists for one of the two kinds of medication. During the treatment there will be regular visits to the clinician in charge. Before onset of medication intake an MRI experiment will be conducted. Subsequentially a transitionperiod of three weeks to Abilify or Risperdal takes place. In this period the current medication is gradually decreased while the intake of the new medicines is gradually increased. Next treatment with new medication will be continued for four weeks. After this period a second MRI experiment will take place.
The fMRI experiments are composed of different tasks which activate the prefrontal cortex. Activity of the prefrontal cortex will be compared between patient groups, before and after use of Abilify and Risperdal. Activity of the prefontal cortex and social cognition should inprove (more) after treatment with aripiprazole. Besides positive and negative symptoms of schizophrenia will the rated with a structured interview, the PANSS.
Besides, 20 healthy controls will be included. They will be subjected to one MRI-session, and no antipsychotics will be administered. On a seperate occassion they will be interviewed with the mini-SCAN. This is a short, diagnostic interview to exclude psychiatric illnessess.

Study burden and risks

The study consists of two MRI experiments with a scantime of 75 minutes, a structured interview (PANSS, 30 minutes) and two questionares. Comparibles studies have been carried out before and were experienced as only being a slight effort for subjects.

The medication that is used is prescribed by a clinician only if this is medically relevant. In case of side effects or increase of symptoms the study will be terminated.

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

People diagnozed for schizophrenia according to DSM-IV. They should not repsond to first choiche treatment or suffer from serious side effects.
Besides, healthy control without high education level.

Exclusion criteria

Subjects with a psychiatric or neurologic disease other than schizophrenia, for which they have been treated. Presence of MRI incompatible implants. For safety reasons female participants who may be pregnant will be excluded.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2008
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Abilify
Generic name:	Aripiprazole
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Risperdal
Generic name:	Risperidone
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	26-06-2007
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
EudraCT	EUCTR2007-002748-79-NL
CCMO	NL17987.042.07