Open, randomized trial of the effect of aripiprazole versus risperidone on social cognition in schizophrenia.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26432

Source
NTR

Brief title
N/A

Health condition

80 schizophrenia patients are randomly assigned to either risperidone (4 mg) or aripiprazole (15 mg). Performance on social cognitive tasks are measured at baseline level and after 8 weeks of treatment.

Sponsors and support

Primary sponsor: Bristol Meijers Squibb

Intervention

Outcome measures

Primary outcome

The effect of treatment with risperidone or aripiprazole on social cognitive processes in patients with schizophrenia is the primary result of this study. These processes are assessed

using computerised cognitive tasks. The objective of the study is to determine which of the two antipsychotics is the most effective against social cognitive deficits.

Secondary outcome

N/A

Study description

Background summary

Impairments in social functioning are a hallmark characteristic of schizophrenia. Deficits in social functioning are present throughout the course of the disorder. Indeed, they are even present before the
onset of psychosis (Davidson et al. 1999) and frequently persist despite antipsychotic treatment (Addington & Addington 2000).

The study of social cognition in schizophrenia examines the
processes underlying social dysfunction (Corrigan & Penn, 2001;
Pinkham et al. 2003). Social cognition has been defined as ?the
mental operations underlying social interactions, which include the
human ability to perceive the intentions and dispositions of others?.
A crucial finding is that performance on social cognition tasks predicts social functioning (Penn et al. 2000; Pinkham et al. 2003).

Brain circuits underlying social cognition concern the ventral striatum, the amygdala, the medial prefrontal and orbitofrontal cortex, anterior cingulate, and insula (Phan et al. 2002; Pinkham et
al. 2003). The importance of dopamine pathways in neural processing in these circuits is well established (Grace 2000).

Until now, antipsychotics have not been able to reverse the social deficits associated with schizophrenia, which might be due to their general antagonist activity at dopamine D2 receptors. We
hypothesize that, because of its unique action as a partial dopamine agonist in brain circuits underlying social cognition,
treatment with aripiprazole will lead to a significant improvement in social cognitive processing compared to risperidone. Computerised behavioral tasks are used to measure

social cognition and
questionnaires and inventories are used to map social functioning in patients with schizophrenia.

Study objective

We hypothesize that, because of its unique action as a partial dopamine agonist in brain circuits underlying social cognition, treatment with aripiprazole will lead to a significant improvement in social cognitive processing compared to risperidone.

Study design

N/A

Intervention

80 schizophrenia patients are randomly assigned to either risperidone (4 mg) or aripiprazole (15 mg).

Contacts

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Eligibility criteria

Inclusion criteria

1. DSM-IV based diagnosis of schizophrenia;

2. Age 18 - 50;

3. Active anticonception;

4. IQ > 80;

5. Negative pregnancy test.

Exclusion criteria

1. Pregnancy;

2. Lactation;

3. Severe head trauma;

4. Substance abuse.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2005
Enrollment:	80
Type:	Actual

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL366
NTR-old	NTR405
Other	: N/A
ISRCTN	ISRCTN61441186

Study results

Summary results
N/A