

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

Submission date 27/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 27/01/2006	Overall study status Completed	☐ Protocol
Last Edited 05/11/2008	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR405

Study information

Scientific Title

Study objectives

We hypothesise 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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Multicentre, randomised, active controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Aripiprazole, risperidone

Primary outcome(s)

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.

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2007

Eligibility

Key inclusion criteria

1. Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) based diagnosis of schizophrenia
2. Aged 18 - 50 years
3. Active contraception
4. Intelligence quotient (IQ) greater than 80
5. Negative pregnancy test

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Pregnancy
2. Lactation
3. Severe head trauma
4. Substance abuse

Date of first enrolment

01/12/2005

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information

Organisation

University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Industry

Funder Name

Bristol-Myers Squibb (The Netherlands)

Alternative Name(s)

Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers Company, BMS

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary