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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

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