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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 [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/01/2006	**Overall study status** Completed	
Last Edited 05/11/2008	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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 measures
No secondary outcome measures

Overall study start date
01/12/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

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)

Sponsor details
P.O. Box 85500
Utrecht
Netherlands
3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Bristol-Myers Squibb (The Netherlands)

Alternative Name(s)

Bristol-Myers Squibb Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration