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

Gepubliceerd: 27-10-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26432

Bron
NTR

Verkorte titel
N/A

Aandoening

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.

Ondersteuning

Primaire sponsor: Bristol Meijers Squibb

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. DSM-IV based diagnosis of schizophrenia;

2. Age 18 - 50;

3. Active anticonception;

4. IQ > 80;

5. Negative pregnancy test.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Lactation;

3. Severe head trauma;

4. Substance abuse.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2005

Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL366
NTR-old	NTR405
Ander register	: N/A
ISRCTN	ISRCTN61441186

Resultaten

Samenvatting resultaten

N/A