Dose reduction or switch to ziprasidone followed by clozapine therapy: what works better in a long stay schizophrenia group?

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Patients treated with ziprasidone reveal fewer negative symptoms on the PANSS negative symptoms sub-scale and/or better scores on the CGI therapeutic effects sub-scale (CGI-TE) than patients treated with low-dose conventional antipsychotics (5 mg/...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24705

Bron
NTR

Verkorte titel
AP Project

Aandoening

therapy refractory schizophrenia and schizoaffective disorders

Ondersteuning

Primaire sponsor: Mental Health Service Rivierduinen;
University Medical Center Utrecht
Overige ondersteuning: Pfizer USA
Mental Health Service Rivierduinen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• PANSS negative symptoms scale
• CGI therapeutic effect scale

Toelichting onderzoek

Doel van het onderzoek

Patients treated with ziprasidone reveal fewer negative symptoms on the PANSS negative symptoms sub-scale and/or better scores on the CGI therapeutic effects sub-scale (CGI-TE) than patients treated with low-dose conventional antipsychotics (5 mg/day haloperidol or equivalent doses).
For patients not effectively treated in this regimen clozapine will be superior.

Onderzoeksopzet

Baseline measurements (Phase A): weeks 0, 6 and 12.
Dose adjustment and switch phase (Phase B): variable, between 0 and 24 weeks following baseline time points.
One-year treatment and observation phase (Phase C): weeks 4, 16, 34 and 52, following dose adjustment and switch phase.

Afterwards patients are treated with clozapine and followed for another year, with evaluations 12 weeks after an adequate plasma level and at the end of the study.

Measurements: symptoms of psychosis (PANSS), clinical impression of symptoms (CGI), depression (MADRS), neurocognitive symptoms (NPO), general functioning (REHAB), social function and aggression (SDAS), extrapyramidal and general side effects (AIMS, Fahn-Marsden, UPDRS, BARS and UKU), subjective well being (SWN), quality of life (MANSA), addiction severity (ASI), weight, length and laboratory measurements.

Onderzoeksproduct en/of interventie

The study consists of three consecutive phases:
12-week pre-switch observation phase (Phase A): during 12 weeks repeated baseline ratings will be done under fixed medication schedules without change of previously used medication (stable baseline measurements).

Dose adjustment and switch phase (Phase B): At random one group of patients (group 1) continues to use conventional antipsychotics. The other group (group 2) is switched to ziprasidone. In group 1 doses of >5mg/day haloperidol equivalents will be reduced to 5 mg/day. Reduction will take a maximum of 24 weeks. Type of antipsychotic and route of administration will not be changed. In group 2, the equivalent of 5 mg/day of haloperidol of the conventional antipsychotic will be replaced by ziprasidone in the first 6 weeks of the double blind treatment phase. The remaining dose of the conventional antipsychotic is reduced similar to group 1.
One-year treatment and observation phase (Phase C): after the dose adjustment and switch phase patients are treated and observed for 52 weeks.

Afterwards patients are treated with clozapine and followed for another year, with evaluations 12 weeks after an adequate plasma level and at the end of the study.

Contactpersonen

Publiek

Valklaan 3

Jan Bogers
Oegstgeest 2342EB
The Netherlands
tel 00 31 71 8908099

Wetenschappelijk

Valklaan 3

Jan Bogers
Oegstgeest 2342EB
The Netherlands
tel 00 31 71 8908099

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-DSM-IV diagnosis of schizophrenia or schizoaffective disorder, based on a SCID interview.

-Use of conventional antipsychotics, p.o. or i.m. (depot-preparations), and the patient consenting to use oral medication.

-Psychotic symptoms having been present during at least the past 2 years, more or less continuously, confirmed by information from the clinical file and the SCID interview.

-Stable symptomatology and no changes in medication during the last 3 months before inclusion.

-Able to comply with the study design.

-Both sexes.

-Age „d18 years.

-In-patients.

-Judicially (R.M. = forced hospitalization) or voluntarily staying in the hospital (I.B.S. excluded).

-Written informed consent from patient and/or representative.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Patients using conventional antipsychotics > 5 mg/day haloperidol equivalents with well documented failures to reduce the dose, because of destabilization.

-Somatic diseases that pose a medical risk (decided by the treating physician); decision based on the known physical condition, information from patient and physician, lab-results (from at least within one year before inclusion: BSE/CRE, blood cells, electrolytes, liver and kidney functions and glucose), a known QTc>500ms (ECG).

-Poor compliance with oral medication.

-patients under I.B.S. (forced hospitalization in crisis for a short time (max 3 weeks))

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2007
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2016
Soort:	Eerste indiening

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	NL5711
NTR-old	NTR5864
Ander register	CCMO : P02.1663L

Resultaten