Clonidine: een veelbelovende toevoeging aan de huidige behandeling van schizofrenie.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20882

Source
Nationaal Trial Register

Brief title
CATS

Health condition

Therapy resistant schizophrenia
Clonidine
Noradrenaline

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Change in " Positive and Negative Symptom Scale (PANSS)" total compared to baseline.

Secondary outcome

-General functioning (tested by "Global Assessment of Functioning", GAF)

-Cognitive functioning (tested by "Brief Assessment in Cognition", BACS and "The Cambridge Neuropsychological Test Automated Battery", CANTAB)

-Depressive symptoms (tested by "Calgary Depression Scale For Schizophrenia", CDSS)

-Safety data will be evaluated by comparing incidences (number and percentage of subjects with at least one occurrence) of key SEAs and SUSARs (e.g. hospitalizations)

-Psychophysiological parameters (tested by "Copenhagen Psychophysiological Test Battery", CPTB)

Study description

Background summary

Schizophrenia is a major debilitating mental disease with an incidence of approximately 1% in the general population worldwide. Currently available antipsychotics are only effective in reducing positive symptoms, without restoring cognition or alleviating negative symptoms. Between one-fifth and one-third of patients have little, if any, benefit from them. Treatment of these patients remains a persistent public health problem, as treatment resistant patients are often highly symptomatic, have a severely reduced quality of life and need extensive periods of hospital care. Therapy-resistant Schizophrenia patients also require a disproportionately high amount of the total health costs for schizophrenia. Clonidine is a noradrenergic α2A agonist, usually prescribed in the treatment of hypertension, but also in the treatment of Tourette’s syndrome and in the treatment of children with ADHD. Results of a recent performed pilot study from our study group and literature point at a potentially positive effect of clonidine on certain aspects of schizophrenia. In our pilot study we found that in schizophrenia patients very often disturbed parameters of basic information processing normalized when they were treated with only one administration of low dose (between 25 and 75 µg) of clonidine. In schizophrenia, there is a correlation between these parameters of basic information processing and cognitive functioning, symptom severity and daily functioning. Therefore we expect that a longer treatment period with clonidine will improve not only positive symptom severity, but also notoriously treatment resistant negative symptomatology. We also expect an improvement in cognitive functioning and daily functioning.

Study objective

-Six weeks of treatment with a supplementary low dose of clonidine to the current medical treatment of clozapine resistant patients will effectively reduce symptom severity and

cognitive impairments in therapy resistant schizophrenia patients

-Following this 6 weeks of treatment patients will show improved day to day functioning

-Clonidine will normalize psychophysiological parameters of basic information processing in clozapine resistant patients with schizophrenia

Study design

Measurements and tests will be performed at baseline, at halftime (3 weeks after baseline) and at the end of the study (6 weeks after baseline)

Intervention

The main investigational product used in this study is clonidine, which is approved for the treatment of several disorders including high blood pressure, migraine and withdrawal symptoms that occur after stopping the use of opiates. -25 patiënts will receive 50 micrograms clonidine once a day for six weeks, added to their own antypsychotics which will preferably kept stable during threatment period. -25 patiënts will receive placebotablets once a day for six weeks, identical looking to the clonidine tablets. Patiënts will continue their own antipsychotica and these will preferably kept stable. -25 healty controls will not undergo any treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. A DSM-IV-R diagnosis of: 295.x (schizophrenia, schizophreniform disorder, or schizoaffective disorder)

2. No or only partial response to clozapine as defined by a total PANSS score of at least 80.

3. Age 18-45 years.

4. Patients are treated with antipsychotic medication

5. Written informed consent Inclusion criteria healthy controls: -Age between 18-45 years - Good Physical and Mental Health meeting criteria "never mentally ill", which will be evaluated with a medical history checklist; -Age between 18 and 45 years; -Written informed consent of the subject.

Exclusion criteria

1. Presence of any of the contra-indications of clonidine as reported in the Summary of Product Characteristics (SPC).

2. Supine systolic blood pressure (SSBP) < 85 mm HG

3. Pre-existent orthostatic hypotension with a drop of systolic blood pressure of > 20 mmHg or a drop of diastolic blood pressure of >10 mmHg. 4. Supine heart rate (SHR) < 50 beats/min

5. Severe brady-arhytmias such as sick-sinussyndroom, second or third degree AV-block. 6. Pregnancy or breast-feeding. A urine pregnancy test will be performed at screening. Exclusion criteria healthy controls: -Current use of any medication; -Any subject who has received any investigational medication within 30 days prior to the start of this study; - History of neurologic illness; History of psychiatric illness in first-degree relatives, evaluated with DSM-IV criteria; -History of alcohol and drug abuse; -Weight below 60 kg.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	75
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4492
NTR-old	NTR4716
Other	:

Study results