

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20882

### Source

NTR

### 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  $\alpha_2A$  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  $\mu$ g) 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 patiënten will receive 50 micrograms clonidine once a day for six weeks, added to their own antipsychotics which will preferably kept stable during threatment period. -25 patiënten will receive placebo tablets once a day for six weeks, identical looking to the clonidine tablets. Patiënten 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-arrhythmias 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