Efficacy of treatment with antipsychotics in patients with psychotic disorder. The value of amino acid profile and neurotrophic proteins.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON31735

Source
ToetsingOnline

Brief title
Amino acids en neurotrophic proteins in psychotic disorder

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Groep Noord en Midden-Limburg

Source(s) of monetary or material Support: eigen ziekenhuis

Intervention

Keyword: Amino acids, antipsychotics, Neurotrophic proteins, Psychosis

Outcome measures

Primary outcome

The BPRS will be used as primary outcome measure. Secondary outcome measures

are the CGI-S and I. A clinical relevant improvement is defined as a reduction

of at least 40% on the BPRS total score..

Secondary outcome

Not applicable

Study description

Background summary

Since the introduction of the atypical antipsychotic risperidone, all marketed novel antipsychotics have been evaluated for their efficacy in patients with (relapsing) psychotic disorder of the schizophrenic type at the Vincent van Gogh Institute for Psychiatry. In general, the efficacy of these compounds appeared to be modest. With respect to biochemical parameters, at baseline plasma levels of glutamate were demonstrated to be enhanced. This increase persisted during the experimental period.
Over the past years the role of the neurotrophic proteins Brain Derived Neurotrophic Factor (BDNF) and S-100B in the pathophysiology of psychotic disorders has been investigated. . Serum levels of BDNF were found to be decreased in patients with schizophrenic or bipolar spectrum disorders whereas treatment with psychotropics resulted in an increase of it. (3,4). Serum levels of S-100B appeared to be enhanced in patients with schizophrenia. However, much is still unknown about the relationship between the neurotrophic proteins BDNF and S-100B and the prognosis of psychotic disorders.

Study objective

De primary objective is to investigate the relationship between serum levels of before mentioned biochemical parameters (amino acid profile and

monoaminergic parameters and the neurotrophic proteins BDNF and S-100B) and the symptomatology at baseline and after 6 weeks standard treatment with an antipsychotic. The secondary objective comprises a detailed evaluation of the symptom profile and the effect of treatment in patients with schizophrenic or bipolar spectrium disorders. The third objective is aimed to establish the efficacy of treatment with antipsychotics in the patient group admitted for (relapsing) psychosis in the psychiatric hospital Vincent van Gogh Institute for Psychiatry.

Study design

Over a period of 2 years at least 100 patients admitted for a (relapse) of their psychotic disorder will be evaluated during 6 weeks while receiving treatment with psychotropics according to the treating psychiatrist. . Selection of the patients will be performed by the treating psychiatrist and the investigator. Symptom profile and effect of treatment will be assessed by means of well known rating scales and will be related to the biochemical parameters (monoamine metabolites and neurotrophic proteins)

Study burden and risks

The burden for participating patients will hardly be different from non-participants, since the regular treatment of the psychiatric hospital will be applied. In order to meet the exclusion criterion of a cytogenetic anomaly, pictures will be taken that will be deleted after evaluation by the clinical genetist. .

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age 18-65
psychotic disorder
legal competence
willing to participate

Exclusion criteria

unable to give informed consent
relevant somatic/neurologic disorder
cytogenetic aberration

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2008
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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
CCMO	NL20469.097.07