Is premorbid functioning a predictor of outcome in patients with early onset psychosis treated with Risperdal Consta?

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The objective of this study is to investigate whether patients with a good premorbid functioning have a beter treatment response after treatment with Risperdal® Consta® than those patients with poor premorbid functioning. Premorbid functioning of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON29863

Source
ToetsingOnline

Brief title
PROPEL Study

Condition

- Schizophrenia and other psychotic disorders

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: door de farmaceutische industrie

Intervention

Keyword: long-acting, psychosis, risperidon, schizophrenia

Outcome measures

Primary outcome

The primary objectise is if patients with a good premorbid functioning have a better treatment response than patients with a bad premorbid functioning as measured by the PANSS total score (Positive And Negative Syndrome Scale) and the CGI-S (Clinical Global Impression of Severity). Changes will be measured from baseline to total end score.

Secondary outcome

The effectiveness of Risperdal® Consta® will be assessed secundarily as follows:

1. Effectivity: CGI-S/C (Severity & Change), PANSS, GAF (Global Assessment of Functioning) and patient retention rate in the study;

2. Patient functioning: SF-36 (short-form 36, to be completed by the patient) and rehospitalization rates;

3. Safety: reported adverse events, ESRS (Extrapyramidal Symptom Rating Scale) and patient retention rate in the study;

4. Insight: SAI-E (Scale for Assessment of Insight - Expended version) and PANSS.

Study description

Background summary

Schizophrenia is a fundamental disorder in psychosocial functioning and is generally chronic. Early intervention with the right treatment can positively

influence the disease outcome of schizophrenia or schizoaffective disorder.

Study objective

The objective of this study is to investigate whether patients with a good premorbid functioning have a beter treatment response after treatment with Risperdal® Consta® than those patients with poor premorbid functioning. Premorbid functioning of the patient will be assessed with the PAS score (Premorbid Adjustment Scale).

Study design

This study is an international, open-label, prospective, multicenter fase IV study.

Intervention

The treatment with Risperdal® Consta® consists of biweekly intramuscular injections with risperidon (startingdose 25 mg). The dose may be increased with an interval of at least 6 weeks and reduced at any time. During the first 3 weeks, patients will be treated with previous antipsychotic mediaction. Prior to inclusion, treatment naïve patients will receive a test dose of oral Risperdal® for 2 days.
During the study, patients will visit the investigator 4 times in total, besides their biweekly treatment, respectively at study entry and subsequently after 6 weeks, 12 weeks and 26 weeks.

Study burden and risks

Patients eligible for this study, are in need of treatment with antipsychotic medication for at least 6 months in the opinion of the investigator. The study burden for the patients have three aspects. Firstly, at the study start en end a medical examination will take place. Secundly, the patient will visit the investigator four times. The investigator will complete several questionnaires and one questionnaire will be completed by the patient following the visits. These are normal procedures for patients with this indication. Finally, the patient will receive biweekly Risperdal® Consta® injections.

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

- Male or female;- Age >18 years;- Primary diagnosis of schizophrenia/schizoaffective disorder according to the Diagnostic and Statistical Manual of Mental Diseases, Fourth Edition (DSM-IV-TR).;- Primary diagnosis for less than 2 years following initial diagnosis and treatment.;- At least 2 previous psychotic episodes.;- Maximum total PANSS score of 80.;- Patients who, in the opinion of the investigator, require at least 6 months treatment with antipsychotic medication.;- Patients may be currently treated with any antipsychotic (with the exception of clozapine and depot neuroleptics) at doses not exceeding the registered highest recommended dose.;- Female patients must be surgically sterile, or practicing an effective method of birth control (e.g. prescription oral contraceptives, contraceptive injections, intra-uterine device, double-barrier method, contraceptive patch, male partner sterilization or abstinence) before entry and throughout the study; and have a negative pregnancy test at baseline, before study entry.;- Patients (or their legally acceptable representatives) must have signed an informed consent document indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study

Exclusion criteria

- DSM-IV-TR Axis I diagnosis other than schizophrenia or schizoaffective disorder.;- Patients

already on treatment with Risperdal Consta.;- Patients requiring treatment at entry with mood stabilizers or antidepressants may enter the study only if a stable dose has been received for 3 months prior to study entry.;- Pregnant or breast-feeding females.;- Patients who have previously received treatment with clozapine.;- Evidence of alcohol or drug dependence (except for nicotine and caffeine dependence according to DSM-IV-TR criteria diagnosed in the last month prior to entry).;- History of severe drug allergy, drug hypersensitivity or neuroleptic malignant syndrome.;- Known hypersensitivity/intolerance or previous non-response to oral risperidone proven by adequate drug plasma levels (non-responders due to non-compliance are not excluded).;- Patients who are known non-responders to previous treatment with at least 2 antipsychotics.;- Serious, unstable and untreated medical illnesses.;- Patients with conditions and symptoms that are listed in the SmPC under special warnings and special precautions for use.;- Patients with mental retardation.;- Known clinically significant ECG abnormality.;- Patients at acute risk of suicide in the investigators opinion at study entry or history of suicidal attempt(s) in the last 3 months before the
study entry.;- Patients having received an experimental drug or used an experimental medical device within 30 days before the planned start of treatment.;- Patients with known phenylketonuria.;- Employees of the investigator or study center, with direct involvement in the proposed study or other studies under the direction of that investigator or study center, as well as family members of the employees or the investigator.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	17
Type:	Anticipated

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Risperdal® Consta®
Generic name:	risperidon
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	24-04-2006
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	23-04-2007
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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
EudraCT	EUCTR2005-004621-25-NL
CCMO	NL11841.028.06