An Open-label Prospective Trial to Explore the Tolerability, Safety and Efficacy of Flexibly Dosed Paliperidone ER in Subjects With Schizophrenia

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The aim of this study is to collect data in a structured way in order to explore the tolerability, safety and efficacy of paliperiode ER with treatment schedules which will be used in future clinical practice.

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

Summary

ID

NL-OMON30663

Source
ToetsingOnline

Brief title
Paliperidone ER flexible dosing in schizophrenia

Condition

- Schizophrenia and other psychotic disorders

Synonym
schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson Pharmaceutical

Source(s) of monetary or material Support: door Janssen-Cilag B.V.

Intervention

Keyword: Flexibly dosed, Paliperidone ER, Schizophrenia

Outcome measures

Primary outcome

PANSS-total score

Secondary outcome

PANSS- subscale scores, percentage responders (>= 20 % improvement in total PANSS score), CGI-S score, PSP scale score, SF-36 scores, patient satisfaction with treatment score, quality of sleep scores, ESRS scores, adverse events, body weight and vital signs.

Study description

Background summary

Registration studies with paliperidone ER are finished and the drug has been proven safe and effective for the treatment of patients with schizophrenia. Only selected patients were allowed to participate in registration studies and the use of concomitant medication was restricted.

Study objective

The aim of this study is to collect data in a structured way in order to explore the tolerability, safety and efficacy of paliperiode ER with treatment schedules which will be used in future clinical practice.

Study design

Patients who signed the informed consent will be screened first. Then, a baseline assessment will be performed and use of paliperidone ER will be started. After 4, 8, 13 and 26 weeks, patients will be asked to return to the study center for follow-up assessments.

Intervention

Existing oral antipsychotics will be stopped immediately or tapered off at the moment treatment with paliperidone ER starts. The recommended starting dose is 6 mg/day. Treatment starts after baseline assessments. Based on response and tolerability doses might be adapted in steps of 3 mg, with a minimum daily dose of 3 mg and a maximum dose of 12 mg.

Study burden and risks

The burden for the patient consists of additional questionnaires to be completed and extra interviews. The risk consists of possible side effects of paliperidone ER. In registration studies, it appeared that adverse events with 3 mg and 6 mg paliperidone ER were comparable to placebo.

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

Subject meets the DSM-IV criteria for schizophrenia; Subject is previously non-acute, i.e. on the same antipsychotic medication used for the treatment of schizophrenia and CGI-S change of 1 or less in the past 4 weeks before enrollment. Subject has been given an adequate dose of an appropriate oral antipsychotic for an adequate period of time prior to enrollment, but previous treatment is considered unsuccessful due to one or more of the following reasons: lack of efficacy, lack of tolerability or safety, lack of compliance and/or other reasons to switch to another antipsychotic medication; · Male or female, aged >= 18 years; · Subject is able to read, understand and sign the Institutional Review Board-approved informed consent form; · Subject is healthy on the basis of a physical examination and vital signs at screening; · Female subjects must be postmenopausal for at least 1 year, surgically sterile, abstinent, or, if sexually active, agree to practice an effective method of birth control before entry and throughout the study. Effective methods of birth control include prescription hormonal contraceptives, contraceptive injections, intrauterine devices, double barrier method, contraceptive patch and male partner sterilization. Female subjects of childbearing potential must also have a negative urine pregnancy test at screening; · Subjects must be willing and able to fill out self-administered questionnaires

Exclusion criteria

On clozapine, any conventional depot neuroleptic or Risperdal CONSTA during the last 3 months; · Serious unstable medical condition, including known clinically relevant laboratory abnormalities; · History or current symptoms of tardive dyskinesia; · History of neuroleptic malignant syndrome; · Judged to be at high risk for adverse events, violence, or self-harm; · Pregnant or breast-feeding female; · Participation in an investigational drug trial in the 30 days prior to selection; · Known hypersensitivity to paliperidone ER or risperidone; · Inability to swallow the study medication whole with the aid of water (subjects may not chew, divide, dissolve, or crush the study medication, as this may affect the release profile); · Employees of the investigator or study center, persons with direct involvement in the proposed study or other studies under the direction of that investigator or study center, or family members of the employees or the investigator; · Subjects with current or known history (over the past 6 months) of substance dependence according to DSM-IV Criteria

Study design

Design

Study phase: 3

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2007
Enrollment:	48
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Invega
Generic name:	paliperidone ER (3, 6 and 12 mg tablets)
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	01-03-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	27-08-2007
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-09-2007
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-09-2008
Application type:	Amendment

Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-10-2008
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	EUCTR2006-004265-34-NL
CCMO	NL15822.028.07
Other	nog niet bekend