Comparison of Paliperidone Palmitate and RISPERDAL CONSTA in Patients With Schizophrenia

ClinicalTrials.gov Identifier: NCT00589914

Recruitment Status : Completed
First Posted : January 10, 2008
Results First Posted : October 4, 2011
Last Update Posted : June 24, 2014

Sponsor:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Information provided by (Responsible Party):
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Study Description

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Brief Summary:
The purpose of this study is to demonstrate the effectiveness of paliperidone palmitate in patients with Schizophrenia.

Condition or disease	Intervention/treatment	Phase
Schizophrenia	Drug: RISPERDAL CONSTA Drug: Paliperidone palmitate	Phase 3

This is a randomized (patients assigned to treatment groups by chance), double-blind (patient and study staff will not know the treatment assignment) study of paliperidone palmitate compared with RISPERDAL CONSTA (Risperidone Long-Acting Intramuscular Injection) in adult patients with schizophrenia. The total duration of the study will be approximately 14 weeks. For those patients without source documentation of tolerability to oral (by mouth) risperidone or paliperidone Extended Release (ER) tablets, injectable RISPERDAL CONSTA or paliperidone palmitate, or those patients who were not currently taking another antipsychotic, a minimum of 4 days and a maximum of 6 days of oral paliperidone ER treatment at a dosage of 6 mg/day will be administered for tolerability testing before the first injection of double-blind (DB) study drug (paliperidone palmitate or RISPERDAL CONSTA). During the DB period, study drug will be administered to patients as an intramuscular (i.m.) injection. Paliperidone palmitate (PP) 150mg equivalent (eq) (and RISPERDAL CONSTA placebo) at Baseline (BL) (Day 1), 100mg eq at Visit (V) 4 (Day 8), 50 or 100mg eq at V7 (Day 36), and 50,100,or 150mg eq at V9 (Day 64) or RISPERDAL CONSTA (RC) 25mg at V4 and V6 (Day 22), 25 or 37.5mg at V7, and 25, 37.5, or 50mg at V9 will be given as i.m. injections. Patients in the RC group will also take risperidone tablets (1-6 mg/day) at BL for 28 days and be given an injection of PP placebo at BL, V1, V7, and V9.

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	1221 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose:	Treatment
Official Title:	A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexible Doses of Paliperidone Palmitate and Flexible Doses of Risperidone Long-Acting Intramuscular Injection in Subjects With Schizophrenia
Study Start Date :	March 2007
Actual Primary Completion Date :	June 2009
Actual Study Completion Date :	June 2009

Resource links provided by the National Library of Medicine NIH NLM

Genetics Home Reference related topics: Schizophrenia

MedlinePlus related topics: Schizophrenia

Drug Information available for: Risperidone Paliperidone Paliperidone Palmitate

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment

Arm	Intervention/treatment
Active Comparator: RISPERDAL CONSTA RISPERDAL CONSTA 25-50 mg eq every 2 weeks	Drug: RISPERDAL CONSTA RISPERDAL CONSTA: Type=exact number, unit=mg, number=25, 37.5, or 50, form=suspension for injection, route=Intramuscular use. One i.m. injection of RISPERDAL CONSTA 25-50 mg eq every 2 weeks at V4, V6, V7, V8, V9, and V10. PALIPERIDONE PALMITATE PLACEBO: Form=suspension for injection, route=Intramuscular use. One i.m. injection every 2 weeks at Baseline and at V4, V7, and V9. RISPERIDONE: Type=up to, unit=mg, number=1 to 6, form=Tablet, route=Oral Use. One tablet for the first 4 weeks (28 days) of the DB treatment period.
Experimental: R092670 Paliperidone Palmitate 50-150 mg eq every 4 wks	Drug: Paliperidone palmitate PALIPERIDONE PALMITATE: Type=exact number, unit=mg, number=50, 100, or 150, form=suspension for injection, route=Intramuscular use. One i.m. injection of Paliperidone palmitate 50-150 mg eq every 4 wks at Baseline, V4, V7, and V9. RISPERDAL CONSTA PLACEBO: Form=suspension for injection, route=Intramuscular use. One i.m. injection every 4 weeks at Baseline, V4, V7, and V9.

Outcome Measures

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Primary Outcome Measures :

1. Change in the Positive and Negative Syndrome Scale (PANSS) Total Score for Schizophrenia [Time Frame: Baseline to the last postrandomization assessment in the double-blind treatment period (approximately 13 weeks)]

   The PANSS scale is used to assess the neuropsychiatric symptoms of schizophrenia. The 30-item PANSS scale provides a total score (sum of the scores of all 30 items) and scores for 3 subscales, the positive subscale (7 items), the negative subscale (7 items),and the general psychopathology subscale (16 items), each item rated on a scale of 1 (absent) to 7 (extreme).

Secondary Outcome Measures :

1. The Change From Baseline for the CGI-S Score [Time Frame: Baseline to the last postrandomization assessment in the double-blind treatment period (approximately 13 weeks)]]

   The CGI-S rating scale is used to rate the severity of a patient's psychotic condition on a 7-point scale ranging from 1 (not ill) to 7 (extremely severe). This scale permits a global evaluation of the patient's condition at a given time. A qualified rater administered the CGI-S

2. The Change From Baseline in the PSP Score [Time Frame: Baseline to the last postrandomization assessment in the double-blind treatment period (approximately 13 weeks)]

   The PSP scale is used to assess the degree of dysfunction a patient exhibits over a 7-day period within 4 domains of behavior: socially useful activities, personal and social relationships, self-care, and disturbing and aggressive behavior. The results of the assessment are converted to a numeric score. A score between 71 and 100 indicates a mild degree of difficulty; a score between 31 and 70 indicates a moderate degree of dysfunction, and a patient with a score of 30 or less has functioning so poor he or she requires intensive supervision.

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Meet diagnostic criteria for schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria as specified by the protocol for at least 1 year before screening
- Prior medical records, written documentation or verbal information obtained from previous psychiatric providers obtained by the investigator must be consistent with the diagnosis of schizophrenia
- A total PANSS score between 60 and 120, inclusive, at screening and baseline; Body mass index (BMI) at the screening visit BMI at least 17 kg/m2
- Female patients must be postmenopausal for at least 2 years, surgically sterile, abstinent, or, if sexually active, be practicing an effective method of birth control before study entry and throughout the study as specified by the protocol. Women of childbearing potential must have a negative serum beta-human chorionic gonadotropin (b hCG) pregnancy test result at screening.

Exclusion Criteria:

- Patient unable to provide consent or involuntarily committed to psychiatric hospitalization; A primary, active DSM-IV diagnosis on Axis I other than schizophrenia
- A DSM-IV diagnosis of active substance dependence within 3 months before screening (nicotine and caffeine are not exclusionary)
- History of treatment resistance as defined by failure to respond to 2 adequate treatments with different antipsychotic

- Relevant history or current presence of any significant or unstable cardiovascular, respiratory, neurologic (including seizures or significant cerebrovascular disease), renal, hepatic, hematologic, endocrine, immunologic, or other systemic disease including history of neuroleptic malignant syndrome; History of any severe pre-existing gastrointestinal narrowing or inability to swallow oral study drug whole with the aid of water (applies to those patients requiring oral tolerability only)
- Significant risk of suicidal or violent behavior, as clinically assessed by the investigator ; History of life-threatening allergic reaction to any drug; Known or suspected hypersensitivity or intolerance to risperidone, paliperidone, 20% Intralipid, or any of their excipients (e.g., soybean oil, egg yolks, phospholipids, and glycerol)
- Have received an experimental drug or experimental biologic, or used an experimental medical device within 6 months before screening; History of any active malignancy within the previous 5 years, with the exception of basal cell carcinomas
- Women who are pregnant or breast-feeding or are planning to become pregnant uring the study

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00589914***

Locations

▸ Show 87 study locations

Sponsors and Collaborators

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Investigators

Study Director: Johnson & Johnson Pharmaceutical Research & Development, L.L. C. Clinical Trial Johnson & Johnsor

More Information

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Additional Information:

A Randomized, Double-Blind, Parallel-Group, Comparative Study of Flexible Doses of Paliperidone Palmitate and Flexible Doses of Risperidone Long-Acting Intramuscular Injection in Subjects With Schizophrenia EXIT

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Alphs L, Bossie CA, Fu DJ, Ma YW, Kern Sliwa J. Onset and persistence of efficacy by symptom domain with long-acting injectable paliperidone palmitate in patients with schizophrenia. Expert Opin Pharmacother. 2014 May;15(7):1029-42. doi: 10.1517/14656566.2014.909409.

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