History of Changes for Study: NCT00210717

A Study to Compare the Effectiveness and Safety of Flexibly Varied Doses of Paliperidone Palmitate and Risperidone in Treating Patients With Schizophrenia

Latest version (submitted June 6, 2011) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 13, 2005	None (earliest Version on record)
2	○	○	October 7, 2005	Contacts/Locations, Eligibility and Study Status
3	○	○	November 10, 2005	Contacts/Locations and Study Status
4	○	○	December 2, 2005	Contacts/Locations and Study Status
5	○	○	January 27, 2006	Contacts/Locations and Study Status
6	○	○	March 3, 2006	Contacts/Locations, Study Status and Eligibility
7	○	○	March 31, 2006	Contacts/Locations and Study Status
8	○	○	April 28, 2006	Study Status
9	○	○	May 26, 2006	Contacts/Locations and Study Status
10	◉	◉	July 3, 2006	Recruitment Status, Study Status and Contacts/Locations
11	○	○	October 11, 2007	Recruitment Status, Study Status and Oversight
12	○	○	June 29, 2009	Study Status, References, Contacts/Locations, Eligibility, Study Design and Study

Version	A	B	Submitted Date	Changes
13	○	○	July 8, 2009	References and Study Status
14	○	○	August 28, 2009	Study Status, References and Study Design
15	○	○	April 26, 2010	Study Status
16	○	○	June 6, 2011	References and Study Status

Compare Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00210717
Submitted Date: July 3, 2006 (v10)

Study Identification

Unique Protocol ID: CR004195

Brief Title: A Study to Compare the Effectiveness and Safety of Flexibly Varied Doses of Paliperidone Palmitate and Risperidone in Treating Patients With Schizophrenia

Official Title: A Randomized, Double-Blind, Parallel Group, Comparative Study of Flexibly Dosed Paliperidone Palmitate (25, 50, 75, or 100 mg eq.) Administered Every 4 Weeks and Flexibly Dosed RISPERDAL CONSTA (25, 37.5, or 50 mg) Administered Every 2 Weeks in Subjects With Schizophrenia

Secondary IDs:

Study Status

Record Verification: June 2006

Overall Status: Active, not recruiting

Study Start: February 2005

Primary Completion:

Study Completion:

First Submitted: September 13, 2005

First Submitted that Met QC Criteria: September 13, 2005

First Posted: September 21, 2005 [Estimate]

Last Update Submitted that Met QC Criteria: July 3, 2006

Last Update Posted: July 4, 2006 [Estimate]

Sponsor/Collaborators

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

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring:

Study Description

Brief Summary: The purpose of this study is to compare the effectiveness and safety over 1 year of treatment of intramuscular injections of paliperidone palmitate and long-acting risperidone in patients with schizophrenia.

Detailed Description: Paliperidone palmitate is being developed as a long-acting intramuscular injectable formulation for the treatment of schizophrenia. Many patients with schizophrenia achieve symptom stability with the available oral antipsychotic medications; however, it is estimated that up to 75% have difficulty adhering to a daily oral treatment regimen. Long-acting injectable formulations may make compliance with the treatment regimen easier by eliminating the need for daily medication. An injectable formulation of risperidone is widely used in the treatment of schizophrenia and has been well tolerated by patients with chronic schizophrenia at the recommended dosage of 25 to 50 milligrams every 2 weeks. The present study is designed to evaluate the comparability of paliperidone palmitate and long-acting injectable risperidone over 1 year of treatment. This is a randomized, double-blind, active-controlled, parallel-group, multicenter comparative study in patients with schizophrenia. The study comprises a screening period of up to 1 week (including periods for washout of psychotropic medications and, if necessary, an oral tolerability test) and a 53-week double-blind treatment period. In the double-blind treatment period, patients will be randomly assigned in equal numbers to receive treatment with either (1) flexibly dosed paliperidone palmitate administered every 4 weeks or (2) flexibly dosed long-acting risperidone administered every 2 weeks. Drug effectiveness and safety will be evaluated periodically throughout the study. Samples for pharmacokinetic evaluation will be collected at designated time points, and a blood sample will be collected at baseline (before the start of the double-blind treatment period) or at any subsequent visit for an optional pharmacogenomic (genetic) analysis. The study hypothesis is that paliperidone palmitate will be as effective as long-acting risperidone in the treatment of patients with schizophrenia.

Paliperidone palmitate (25, 50, 75, or 100 milligrams (mg) equivalent) every 4 weeks, or long-acting risperidone 25, 37.5, or 50 mg every 2 weeks of double-blind treatment period, injected into the gluteal muscle (buttocks). Oral risperidone (1-6 mg) first 4 weeks of double-blind period

Conditions

Conditions: Schizophrenia

Keywords: paliperidone palmitate
antipsychotic agents
dementia praecox
risperidone
intramuscular injection
mental disorders

schizophrenia
PANSS

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	
Masking:	Double (masked roles unspecified)
Allocation:	Randomized
Enrollment:	700

Arms and Interventions

Intervention Details:

Drug: paliperidone palmitate

Outcome Measures

Primary Outcome Measures:

1. The change in the total score of the Positive and Negative Syndrome Scale (PANSS) from the beginning to the end of the double-blind treatment period or to the last post-randomization assessment.

Secondary Outcome Measures:

2. The investigator's Clinical Global Impression of the Severity (CGI-S) of schizophrenia and rating of mental function on a Personal and Social Performance Scale (PSP). Evaluations of adverse events, laboratory tests, and other measures of drug safety.

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- A diagnosis of schizophrenia (disorganized, catatonic, paranoid, residual, or undifferentiated types) according to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM IV) for at least 1 year before the screening evaluation
- a total PANSS score of 60 to 120 at screening and baseline (pre-treatment) evaluations
- A body mass index (BMI [weight (kilograms)]/[height (meters)]²) of at least 15.0 kg/m²

Exclusion Criteria:

- A primary active DSM-IV Axis I diagnosis other than schizophrenia

- a DSM-IV diagnosis of active substance dependence within 3 months of screening evaluation
- a history of treatment resistance as defined by failure to respond to 2 adequate trials of different antipsychotic medications
- A woman who is pregnant, breast-feeding, or planning to become pregnant during the study period

Contacts/Locations

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

Locations:

IPDSharing

Plan to Share IPD:

References

Citations: Fleischhacker WW, Gopal S, Lane R, Gassmann-Mayer C, Lim P, Hough D, Remmerie B, Eerdekens M. A randomized trial of paliperidone palmitate and risperidone long-acting injectable in schizophrenia. Int J Neuropsychopharmacol. 2012 Feb;15(1):107-18. doi: 10.1017/S1461145711001076. Epub 2011 Jul 22. Erratum in: Int J Neuropsychopharmacol. 2012 Feb;15(1):119. Dosage error in article text. PubMed 21777507

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top