History of Changes for Study: NCT00210548

A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects 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 19, 2005	Contacts/Locations, Eligibility and Study Status
3	○	○	December 2, 2005	Contacts/Locations and Study Status
4	○	○	January 27, 2006	Contacts/Locations and Study Status
5	○	○	March 3, 2006	Contacts/Locations, Study Status and Eligibility
6	○	○	March 31, 2006	Contacts/Locations and Study Status
7	○	○	April 28, 2006	Study Status
8	○	○	May 26, 2006	Contacts/Locations and Study Status
9	○	○	July 3, 2006	Study Status and Contacts/Locations
10	○	○	September 1, 2006	Contacts/Locations and Study Status
11	◉	◉	October 6, 2006	Study Status, Contacts/Locations and Oversight
12	○	○	March 12, 2007	Study Status

Version	A	B	Submitted Date	Changes
13	○	○	April 1, 2007	Recruitment Status, Contacts/Locations and Study Status
14	○	○	October 11, 2007	Recruitment Status, Study Status and Contacts/Locations
15	○	○	August 27, 2009	Study Status, Study Design, References, Contacts/Locations, Eligibility and Study Description
16	○	○	November 19, 2009	Study Status and Study Design
17	○	○	April 26, 2010	Study Status
18	○	○	June 6, 2011	References and Study Status

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

Scroll up to access the controls

Study NCT00210548
Submitted Date: October 6, 2006 (v11)

Study Identification

Unique Protocol ID: CR002353

Brief Title: A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects With Schizophrenia

Official Title: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Response Study to Evaluate the Efficacy and Safety of 3 Fixed Doses (50 mg eq., 100 mg eq., and 150 mg eq.) of Paliperidone Palmitate in Subjects With Schizophrenia

Secondary IDs:

Study Status

Record Verification: October 2006

Overall Status: Recruiting

Study Start: April 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: October 6, 2006

Last Update Posted: October 11, 2006 [Estimate]

Sponsor:	Johnson & Johnson Pharmaceutical Research & Development, L.L.C.
Responsible Party:	
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 evaluate the effectiveness and safety of 3 doses of paliperidone palmitate in treating subjects with schizophrenia.
Detailed Description:	This is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, dose-response study of patients who have a Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM IV) diagnosis of schizophrenia. The duration of the study is approximately 14 weeks, including a screening period of 1 week and a 13-week double-blind treatment period. Efficacy 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 double-blind treatment) for an optional pharmacogenomics (genetics) analysis. The hypothesis is that the 3 fixed doses of paliperidone are each more efficacious than placebo in treating subjects with schizophrenia. The effectiveness is measured primarily by the change in the Positive and Negative Syndrome Scale for Schizophrenia (PANSS), and secondarily, by the investigator's Clinical Global Impression of Severity (CGI-S) and by the investigator's evaluation of the patient on a Personal and Social Performance (PSP) Scale. Four injections of paliperidone palmitate 50, 100, or 150 milligrams equivalent administered in the gluteal muscle (buttocks). Injections will be given on Days 1, 8, 36, and 64 of the double-blind treatment period of the study.

Conditions

Conditions:	Schizophrenia
Keywords:	dementia praecox schizophrenia paliperidone palmitate antipsychotic agents PANSS. intramuscular injection mental disorders

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Allocation: Randomized

Enrollment: 376

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 for Schizophrenia (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 DSM-IV diagnosis of schizophrenia (disorganized, catatonic, paranoid, residual, or undifferentiated type) for at least 1 year before the screening evaluation
- a total PANSS score of 70 to 120 at screening and baseline (pre-treatment) evaluations
- a body mass index (BMI [weight (kilograms)]/[height (meters)]^2) of more than 17.0 kg/m^2

Exclusion Criteria:

- A primary active DSM-IV Axis I diagnosis other than schizophrenia
- a decrease of 25% or more in the total PANSS score between screening and baseline evaluations
- 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

Central Contact: Use link at the bottom of the page to see if you qualify for an enrolling site (see list). If you still have questions:

Email: info1@veritasmedicine.com

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

Locations: **United States, California**

Collaborative NeuroScience Network
[Recruiting]
Garden Grove, California, United States, 92845
Contact: David Walling 714-799-7799
Principal Investigator: David Walling

[Active, not recruiting]
Pasadena, California, United States, 91107

[Active, not recruiting]
San Diego, California, United States, 92123

United States, Florida

[Active, not recruiting]
North Miami, Florida, United States, 33161

United States, Illinois

[Active, not recruiting]
Chicago, Illinois, United States, 60640

[Active, not recruiting]
Hoffman Estate, Illinois, United States, 60194

United States, Indiana

[Active, not recruiting]
Indianapolis, Indiana, United States, 46222

United States, Kansas

[Active, not recruiting]
Wichita, Kansas, United States, 67214

United States, Louisiana

[Active, not recruiting]
Lake Charles, Louisiana, United States, 70601

United States, Maryland

[Active, not recruiting]
Towson, Maryland, United States, 21286

United States, Mississippi

[Active, not recruiting]
Flowood, Mississippi, United States, 39232

United States, New Jersey

[Active, not recruiting]
Clementon, New Jersey, United States, 08021

United States, New York

[Active, not recruiting]
Holliswood, New York, United States, 11423

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