

**History of Changes for Study: NCT00101634****Safety and Efficacy of an Anti-Psychotic Versus Placebo in 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	<input type="radio"/>	<input type="radio"/>	<u>June 23, 2005</u>	None (earliest Version on record)
2	<input type="radio"/>	<input type="radio"/>	<u>August 8, 2005</u>	Contacts/Locations, Study Design and Study Status
3	<input checked="" type="radio"/>	<input checked="" type="radio"/>	<u>September 21, 2005</u>	Contacts/Locations and Study Status
4	<input type="radio"/>	<input type="radio"/>	<u>November 29, 2005</u>	Recruitment Status, Study Status, Contacts/Locations, Outcome Measures and Study Design
5	<input type="radio"/>	<input type="radio"/>	<u>January 2, 2007</u>	Recruitment Status, Study Status and Contacts/Locations
6	<input type="radio"/>	<input type="radio"/>	<u>February 26, 2008</u>	Study Status and Study Identification
7	<input type="radio"/>	<input type="radio"/>	<u>February 28, 2008</u>	Study Status, Contacts/Locations, Outcome Measures, Study Description, Study Identification, Eligibility, Arms and Interventions, Study Design, Conditions and Oversight
8	<input type="radio"/>	<input type="radio"/>	<u>August 27, 2009</u>	Study Design, Study Status, References, Contacts/Locations, Eligibility and Study Description
9	<input type="radio"/>	<input type="radio"/>	<u>November 19, 2009</u>	Study Status
10	<input type="radio"/>	<input type="radio"/>	<u>April 26, 2010</u>	Study Status

**Compare**Comparison Format:  Merged  
 Side-by-Side[Scroll up to access the controls](#)**Study NCT00101634****Submitted Date: September 21, 2005 (v3)****Study Identification**

Unique Protocol ID: R092670-PSY-3004

Brief Title: Safety and Efficacy of an Anti-Psychotic Versus Placebo in 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 (25 mg eq, 50 mg eq, and 100 mg eq) of Paliperidone Palmitate in Subjects With Schizophrenia

Secondary IDs:

**Study Status**

Record Verification: September 2005

Overall Status: Recruiting

Study Start:

Primary Completion:

Study Completion:

First Submitted: January 12, 2005

First Submitted that Met QC Criteria: January 12, 2005

Met QC Criteria:

First Posted: January 13, 2005 [Estimate]

Last Update Submitted that Met QC Criteria: September 21, 2005

Met QC Criteria:

Last Update Posted: September 23, 2005 [Estimate]

**Sponsor/Collaborators**

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

Responsible Party:

Collaborators:

**Oversight**

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring:

**Study Description**

effects of the study medication compared to placebo in the treatment of the symptoms of schizophrenia in adults.

**Detailed Description:****Conditions**

Conditions: Schizophrenia

Keywords: Schizophrenia  
psychosis

**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:

**Arms and Interventions****Intervention Details:**

Drug: R092670/Placebo

**Outcome Measures****Eligibility**

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

**Criteria: Inclusion Criteria:**

- Adults aged 18 years and older
- Met diagnostic criteria for schizophrenia according to DSM-IV for at least 1 year before screening
- Body mass index (BMI) of  $>15.0$  kg/m<sup>2</sup>
- Women of childbearing potential must have a negative urine pregnancy before receiving a dose of study drug
- Must be healthy based on medical exam, laboratory tests, and electrocardiogram

**Exclusion Criteria:**

- Subjects who are unable to provide their own consent or who have been involuntarily committed to psychiatric hospitalization
- Acute or unstable medical conditions

- Significant risk of suicidal, homicidal or violent ideation or behavior as clinically assessed by the investigator
- Woman who is pregnant, breast-feeding, or planning to become pregnant during the study period
- Primary active DSM-IV Axis I diagnosis other than schizophrenia

**Contacts/Locations****Locations: United States, California**

[Recruiting]

Cerritos, California, United States, 90814

Contact: Study Contact 562-402-3102

[Recruiting]

La Mesa, California, United States, 91942

Contact: Study Contact 619-667-4568

[Recruiting]

Los Angeles, California, United States, 90011

Contact: Study Contact 714-224-8262

[Recruiting]

Oceanside, California, United States, 92056

Contact: Study Contact 760-631-3056

[Recruiting]

San Marino, California, United States, 91108

Contact: Study Contact 6264058808

[Recruiting]

Santa Ana, California, United States, 92705

Contact: Study Contact 714-547-4100

**United States, District of Columbia**

[Recruiting]

Washington, District of Columbia, United States, 20016

Contact: Study Contact 202-885-5666

**United States, Florida**

[Recruiting]

Jacksonville, Florida, United States, 32256

Contact: Study Contact 904-673-2998

[Recruiting]

Leesburg, Florida, United States, 34748

Contact: Study Contact 352-315-7817

[Recruiting]

South Miami, Florida, United States, 33143

Contact: Study Contact 305-669-6166

**United States, Georgia**

[Recruiting]

Atlanta, Georgia, United States, 30308

Contact: Study Contact 404-881-5800

Augusta, Georgia, United States, 30912  
Contact: Study Contact 706-721-7968

**United States, Illinois**

[Recruiting]  
Oak Brook, Illinois, United States, 60523  
Contact: Study Contact 6309281000

**United States, Louisiana**

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Shreveport, Louisiana, United States, 71101  
Contact: Study Contact 318-227-9600

**United States, New Jersey**

[Recruiting]  
Kenilworth, New Jersey, United States, 07033  
Contact: Study Contact 908-241-1022

**United States, New Mexico**

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Albuquerque, New Mexico, United States, 87111  
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**United States, New York**

[Recruiting]  
Lawrence, New York, United States, 11559  
Contact: Study Contact 516-295-7230

**United States, Ohio**

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Cincinnati, Ohio, United States, 45267-0559  
Contact: Study Contact 513-558-4615

**United States, Oklahoma**

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Oklahoma City, Oklahoma, United States, 73118

**United States, Texas**

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Desoto, Texas, United States, 75115  
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**United States, Virginia**

[Recruiting]  
Falls Church, Virginia, United States, 22044  
Contact: Study Contact 7035316179

**United States, Wisconsin**

[Recruiting]  
Milwaukee, Wisconsin, United States, 53295  
Contact: Study Contact 4143842000

**Bulgaria**

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