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Trial record **11 of 12** for: Vimpat | Studies received from 01/01/2000 to 01/01/2007
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A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Trial to Investigate the Efficacy and Safety of SPM 927 (200mg/Day and 400mg/Day) as Adjunctive Therapy in Subjects With Partial Seizures With or Without Secondary Generalization

This study has been completed.

Sponsor:
UCB Pharma

Information provided by:
UCB Pharma

ClinicalTrials.gov Identifier:
NCT00220415

First received: **August 30, 2005**
Last updated: September 19, 2014
Last verified: February 2010
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

Male and female patients between 16 and 70 years of age who are diagnosed with epilepsy with partial seizures and are taking up to 3 medications for this medical condition will take part in this research study at approximately 80 different locations in Australia and Europe.

The purpose of this study is to evaluate the effectiveness, safety and tolerability of consistent dosages of study drug (**lacosamide**) taken orally twice a day for about 4 months.

Each patient who qualifies and chooses to participate in the study will receive placebo (inactive drug) or gradually increasing doses of **lacosamide** (SPM 927) up to the target dose of 200mg/day or 400mg/day. The target dose or placebo will be maintained for 12 weeks.

The study clinic visits will include a medical history and physical exam, ECG, blood and urine sample collection, and completion of a seizure diary.

Patients who complete the study may enroll in an extension trial and receive active study drug.

Condition	Intervention	Phase
Partial Seizures With or Without Secondary Generalization	Drug: SPM 927	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Double-Blind
Primary Purpose: Treatment

Official Title: A Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group Trial to Investigate the Efficacy and Safety of SPM 927 (200mg/Day and 400mg/Day) as Adjunctive Therapy in Subjects With Partial Seizures With or Without Secondary Generalization

Resource links provided by NLM:

MedlinePlus related topics: Seizures

U.S. FDA Resources

Further study details as provided by UCB Pharma:

Study Start Date: May 2004

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Eligibility

Ages Eligible for Study: 16 Years to 70 Years (Child, Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- partial seizures with or without secondary generalization

Exclusion Criteria:

- subjects received SPM 927 in a previous trial

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00220415

Locations

Germany

Schwarz
Monheim, Germany

Sponsors and Collaborators

UCB Pharma

Investigators

Study Director: UCB Clinical Trial Call Center UCB Pharma

More Information

Additional Information:

Clinical Study Summary on UCB.com

Publications:

Halász P, Kälviäinen R, Mazurkiewicz-Beldzińska M, Rosenow F, Doty P, Hebert D, Sullivan T; SP755 Study Group.. Adjunctive lacosamide for partial-onset seizures: Efficacy and safety results from a randomized controlled trial. Epilepsia. 2009 Mar;50(3):443-53. doi: 10.1111/j.1528-1167.2008.01951.x.

Sake JK, Hebert D, Isojärvi J, Doty P, De Backer M, Davies K, Eggert-Formella A, Zackheim J. A pooled analysis of lacosamide clinical trial data grouped by mechanism of action of concomitant antiepileptic drugs. CNS Drugs. 2010 Dec;24(12):1055-68. doi: 10.2165/11587550-000000000-00000.

Borghs S, de la Loge C, Cramer JA. Defining minimally important change in QOLIE-31 scores: estimates from three placebo-controlled lacosamide trials in patients with partial-onset seizures. Epilepsy Behav. 2012 Mar;23(3):230-4. doi: 10.1016/j.yebeh.2011.12.023.

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

Biton V, Gil-Nagel A, Isojarvi J, Doty P, Hebert D, Fountain NB. Safety and tolerability of lacosamide as adjunctive therapy for adults with partial-onset seizures: Analysis of data pooled from three randomized, double-blind, placebo-controlled clinical trials. Epilepsy Behav. 2015 Nov;52(Pt A):119-27. doi: 10.1016/j.yebeh.2015.09.006.

ClinicalTrials.gov Identifier: NCT00220415 History of Changes
Other Study ID Numbers: SP0755 2004-000290-58
Study First Received: **August 30, 2005**
Last Updated: September 19, 2014
Health Authority: Germany: Federal Institute for Drugs and Medical Devices

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ClinicalTrials.gov processed this record on November 10, 2016

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