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Trial record **1 of 5** for: baclofen ER

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# Efficacy and Safety of Baclofen ER Capsules (GRS) in Subjects With Spasticity Due to Multiple Sclerosis

**This study is currently recruiting participants.**

*Verified January 2013 by Sun Pharma Advanced Research Company Limited*

**Sponsor:**
Sun Pharma Advanced Research Company Limited

**Information provided by (Responsible Party):**
Sun Pharma Advanced Research Company Limited

**ClinicalTrials.gov Identifier:**
NCT01457352

First received: October 17, 2011
Last updated: January 18, 2013
Last verified: January 2013
History of Changes

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

## Purpose

The purpose of this study is to assess whether **baclofen ER** capsules demonstrate efficacy and safety in the treatment of spasticity.

| Condition | Intervention | Phase |
|---|---|---|
| Spasticity | Drug: **Baclofen ER** Capsules<br>Drug: Placebo GRS | Phase 3 |

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Placebo-controlled Randomized Withdrawal Evaluation of the Efficacy and Safety of **Baclofen ER** Capsules (GRS) in Subjects With Spasticity Due to Multiple Sclerosis

**Resource links provided by NLM:**

MedlinePlus related topics: Multiple Sclerosis

Drug Information available for: Baclofen

U.S. FDA Resources

**Further study details as provided by Sun Pharma Advanced Research Company Limited:**

Primary Outcome Measures:

- The primary efficacy outcome is the proportion of subjects who become a treatment failure during double-blind randomized withdrawal [ Time Frame: Week 22 ] [ Designated as safety issue: No ]
- Determining the safety profile when administered over >12 weeks [ Time Frame: Week 22 ] [ Designated as safety issue: Yes ]

Secondary Outcome Measures:

- Subject Global Impression of Severity (SGIS)assessment [ Time Frame: Week 22 ] [ Designated as safety issue: No ]

Estimated Enrollment: 300
Study Start Date: September 2012

Estimated Study Completion Date: June 2014
Estimated Primary Completion Date: April 2014 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| Experimental: **Baclofen ER** Capsules<br>Subjects will receive open-label **Baclofen ER** Capsules (GRS), as a single capsule (unless otherwise noted) for up to 16 weeks in an open-label fashion and **Baclofen ER** Capsules (GRS) or placebo in a double-blind fashion for up to an additional 4 weeks, consistent with the down-titration schedule. | Drug: **Baclofen ER** Capsules<br>Subjects will receive open-label **Baclofen ER** Capsules (GRS), as a single capsule (unless otherwise noted) for up to 16 weeks in an open-label fashion and **Baclofen ER** Capsules (GRS) or placebo in a double-blind fashion for up to an additional 4 weeks, consistent with the down-titration schedule<br>Other Name: **Baclofen ER** |
| Placebo Comparator: Placebo GRS<br>All subjects randomized to the placebo arm will receive Placebo GRS. | Drug: Placebo GRS<br>All subjects randomized to the placebo arm will receive Placebo GRS.<br>Other Name: Placebo |

## Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- Men and women age 18 years and older
- Women of child bearing potential practicing an acceptable method of birth control for the duration of the study as judged by the investigator(s) [such as condoms, foams, jellies, diaphragm, intrauterine device (IUD), oral or long acting injected contraceptives, bilateral tubal ligation or vasectomized partner] for at least 3 months prior to study entry OR postmenopausal for at least 1 year OR surgically sterile (bilateral oophorectomy or hysterectomy)
- If female, negative pregnancy test
- Known history of spasticity due to MS prior to starting baclofen
- A stable daily dose of Baclofen IR, ranging from 30 to 60 mg/day (i.e., same dose given in the same schedule for last 30 days)
- Able and willing to comply with the protocol, including availability for a scheduled clinic visits
- Willingness and giving of written informed consent

Exclusion Criteria:

- History of hypersensitivity to baclofen
- In relapse or history of unstable course over the prior 30 days prior to the Screening Visit
- Concomitant neurologic conditions causing spasticity
- Has received an investigational drug or device within 30 days that would interfere with the study goals prior to the Screening Visit
- Unable to comply with study procedures in the opinion of the investigator
- Has had major surgery within 3 months prior to Screening visit that may affect spasticity assessments such as abdominal surgery, back surgery, or lower leg or knee surgeries

## Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01457352

**Contacts**

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**Locations**

**United States, District of Columbia**

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Washington, District of Columbia, United States, 20007
Contact: Erika Mitchell, NP
Principal Investigator: Carlo Tornatore, MD

**Sponsors and Collaborators**

Sun Pharma Advanced Research Company Limited

**Investigators**

Study Director: Shravanti Bhowmik, MD Sun Pharma Advanced Research Centre Ltd, India

## More Information

No publications provided

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|---|---|
| Responsible Party: | Sun Pharma Advanced Research Company Limited |
| ClinicalTrials.gov Identifier: | NCT01457352 History of Changes |
| Other Study ID Numbers: | CLR_09_21 |
| Study First Received: | October 17, 2011 |
| Last Updated: | January 18, 2013 |
| Health Authority: | United States: Food and Drug Administration |

Keywords provided by Sun Pharma Advanced Research Company Limited:
**Baclofen**, spasticity

Additional relevant MeSH terms:

**Baclofen**
Multiple Sclerosis
Muscle Spasticity
Sclerosis
Demyelinating Autoimmune Diseases, CNS
Autoimmune Diseases of the Nervous System
Nervous System Diseases
Demyelinating Diseases
Autoimmune Diseases
Immune System Diseases
Muscular Diseases
Musculoskeletal Diseases
Muscle Hypertonia
Neuromuscular Manifestations
Neurologic Manifestations
Signs and Symptoms
Pathologic Processes
GABA-B Receptor Agonists
GABA Agonists
GABA Agents
Neurotransmitter Agents
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions
Physiological Effects of Drugs
Muscle Relaxants, Central
Neuromuscular Agents
Peripheral Nervous System Agents
Central Nervous System Agents
Therapeutic Uses

ClinicalTrials.gov processed this record on January 24, 2013