

Phase 3 Study of Dexpramipexole in ALS (EMPOWER)

This study is currently recruiting participants.

Verified on April 2011 by Biogen Idec

First Received on January 20, 2011. Last Updated on April 21, 2011 [History of Changes](#)

Sponsor:	Biogen Idec
Information provided by:	Biogen Idec
ClinicalTrials.gov Identifier:	NCT01281189

► Purpose

The purpose of this study is to determine whether **dexpramipexole** (150 mg twice daily) is safe and effective in the treatment of Amyotrophic Lateral Sclerosis (ALS).

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Amyotrophic Lateral Sclerosis	Drug: Dexpramipexole Drug: Placebo	Phase III

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Safety and Efficacy of **Dexpramipexole** in Subjects With Amyotrophic Lateral Sclerosis

Resource links provided by NLM:

[Genetics Home Reference](#) related topics: [amyotrophic lateral sclerosis](#)

[MedlinePlus](#) related topics: [Amyotrophic Lateral Sclerosis](#)

[U.S. FDA Resources](#)

Further study details as provided by Biogen Idec:

Primary Outcome Measures:

- A joint rank of functional outcomes adjusted for mortality. [Time Frame: 12 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Time to death using all available follow-up data. [Time Frame: 18 months] [Designated as safety issue: No]
- Respiratory decline: time to reach 50% of predicted upright SVC or death. [Time Frame: 18 months] [Designated as safety issue: No]
- Change in ALS-related health quality, as measured by change in the total score on the Amyotrophic Lateral Sclerosis Assessment Questionnaire-5-Item Form (ALSAQ-5) [Time Frame: 18 months] [Designated as safety issue: No]
- Change in muscle strength measurements (MSM), as determined by the overall megascore for hand-held dynamometry (HHD) [Time Frame: 12 months] [Designated as safety issue: No]
- Incidence of adverse events, serious adverse events, vital signs, clinical laboratory assessments, physical examination, electrocardiogram tests, and body weight. [Time Frame: 18 months] [Designated as safety issue: Yes]
- Population pharmacokinetics. [Time Frame: 6 months] [Designated as safety issue: No]

Estimated Enrollment: 804

Study Start Date: March 2011

Estimated Study Completion Date: February 2013

Estimated Primary Completion Date: January 2013 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
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Dexpramipexole: Experimental Intervention: Drug: Dexpramipexole	Drug: Dexpramipexole Oral tablet 150mg twice daily for up to 18 months. Other Name: BIIB050
Placebo: Placebo Comparator Intervention: Drug: Placebo	Drug: Placebo Oral tablet twice daily for up to 18 months.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Aged 18 to 80 years old, inclusive, on Day 1.
- Diagnosis of sporadic or familial ALS.
- Onset of first ALS symptoms within 24 months prior to Day 1.
- World Federation of Neurology El Escorial criteria are met for a possible, laboratory-supported probable, probable, or definite ALS diagnosis.
- Upright slow vital capacity (SVC) of 65% or more at screening.
- Patients taking or not taking Riluzole are eligible for this study: if a patient has never taken Riluzole, he or she is eligible; if a patient is currently taking Riluzole, he or she must have been on a stable dose for at least 60 days; if a patient has discontinued Riluzole, he or she must have stopped taking it for at least 30 days.
- Must be able to swallow tablets at the time of study entry.

Exclusion Criteria:

- Other medically significant illness.
- Clinically significant abnormal laboratory values.
- Pregnant women or women breastfeeding.
- Prior exposure to dexpramipexole.
- Currently taking pramipexole or other dopamine agonists.

Other protocol-defined inclusion/exclusion criteria may apply.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01281189

Contacts

Contact: Medical Director EMPOWER Study

ALSclinicaltrials@biogenidec.com

Contact: and
www.ALSclinicaltrials.com/EMPOWER

 **Hide Study Locations**
Locations

United States, Arizona

Barrow Neurological Institute - St. Joseph's Hospital

**Not yet
recruiting**

Phoenix, Arizona, United States, 85013

Contact: Gale Kittle 602-406-4792 gale.kittle@chw.edu

Principal Investigator: Shafeeq Ladha, MD

United States, Arkansas

University of Arkansas for Medical Sciences

**Not yet
recruiting**

Little Rock, Arkansas, United States

United States, California

University of California at San Francisco - Fresno

**Not yet
recruiting**

Fresno, California, United States

University of California, Irvine

**Not yet
recruiting**

Orange, California, United States

University of California, Davis

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recruiting**

Sacramento, California, United States, 95817

Contact: Steffany Lim 916-734-6265 steffany.lim@ucdmc.ucdavis.edu

Principal Investigator: Björn Oskarsson, MD

California Pacific Medical Center

**Not yet
recruiting**

San Francisco, California, United States

United States, Connecticut

Hospital for Special Care

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recruiting**

New Britain, Connecticut, United States, 6053

Contact: Lavanya Rajachadran 860-612-6349

lrachadran@hfsc.org

Principal Investigator: Jinsy Andrews, MD

United States, Florida

Mayo Clinic - Jacksonville

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recruiting**

Jacksonville, Florida, United States, 32224
Contact: Amelia Johnston 904-953-6912
mayofloridaalsresearch@mayo.edu
Principal Investigator: Kevin Boylan, MD

University of Miami Miller School of Medicine

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recruiting**

Miami, Florida, United States, 33136
Contact: Julie Steele 305-242-7424 jsteele@med.miami.edu
Principal Investigator: Khema Sharma, MD

University of South Florida Medical Center

**Not yet
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Tampa, Florida, United States, 33612
Contact: Sharon Usher 813-396-9004
Principal Investigator: Tuan Vu, MD

United States, Georgia

Emory University

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Contact: Meraida Polak 404-778-3807 mpolak@emory.edu
Principal Investigator: Jonathan Glass, MD

United States, Illinois

Northwestern University

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Chicago, Illinois, United States

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Indiana University

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Principal Investigator: Robert Pascuzzi, MD

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University of Iowa

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Iowa City, Iowa, United States

United States, Kansas

University of Kansas Medical Center

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Kansas City, Kansas, United States, 66160

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Contact: Laura Herbelin lherbelin@kumc.edu

Principal Investigator: Richard Barohn, MD

United States, Maryland

Johns Hopkins University School of Medicine

**Not yet
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Baltimore, Maryland, United States

United States, Massachusetts

Massachusetts General Hospital

Recruiting

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Principal Investigator: Nazem Atassi, MD

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Principal Investigator: Deborah Gelinias, MD

United States, Minnesota

Hennepin County Medical Center

**Not yet
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Minneapolis, Minnesota, United States

Mayo Clinic - Rochester

**Not yet
recruiting**

Rochester, Minnesota, United States

United States, Missouri

Washington University School of Medicine

**Not yet
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St Louis, Missouri, United States, 63110

Contact: Charlie Wulf 314-362-6980 wulfc@neuro.wustl.edu

Contact: Pam Townsend townsendp@neuro.wustl.edu

Principal Investigator: Alan Pestronk, MD

United States, Nebraska

Neurology Associates, P.C.

Recruiting

Lincoln, Nebraska, United States

United States, Nevada

University of Nevada School of Medicine

Las Vegas, Nevada, United States, 89102
Contact: Margie Hyderkhan 702-671-5093
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Principal Investigator: David Ginsburg, MD

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United States, New Hampshire

Dartmouth-Hitchcock Medical Center

Lebanon, New Hampshire, United States, 3756
Contact: Faith Alexandre 603-650-4241
Principal Investigator: Elijah Stommel, MD

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recruiting**

United States, New York

Columbia University

New York, New York, United States, 10032
Contact: Nicole Armstrong 212-305-8148 na2398@columbia.edu
Contact: Yei-Won Lee
Principal Investigator: Hiroshi Mitsumoto, MD

**Not yet
recruiting**

Research Foundation of the State University of New York
Syracuse, New York, United States

Recruiting

United States, North Carolina

Carolinas Medical Center

Charlotte, North Carolina, United States

**Not yet
recruiting**

Duke University Medical Center

Durham, North Carolina, United States

**Not yet
recruiting**

Wake Forest University

Winston-Salem, North Carolina, United States, 27157
Contact: Mozhdeh Marandi 336-713-8577 mmarandi@wfubmc.edu
Principal Investigator: James Caress, MD

**Not yet
recruiting**

United States, Ohio

The Cleveland Clinic Foundation

Cleveland, Ohio, United States

**Not yet
recruiting**

Ohio State University
Columbus, Ohio, United States

**Not yet
recruiting**

United States, Oregon

Providence ALS Center
Portland, Oregon, United States

**Not yet
recruiting**

United States, Pennsylvania

Penn State Hershey Medical Center
Hershey, Pennsylvania, United States, 17033
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hstephens1@hmc.psu.edu
Principal Investigator: Zachary Simmons, MD

**Not yet
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Drexel University College of Medicine
Philadelphia, Pennsylvania, United States

**Not yet
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ALS Center at Penn
Philadelphia, Pennsylvania, United States

**Not yet
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University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania, United States

Recruiting

United States, Tennessee

Vanderbilt University Medical Center
Nashville, Tennessee, United States, 37232
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Principal Investigator: Peter Donofrio, MD

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United States, Texas

Texas Neurology
Dallas, Texas, United States, 75214
Contact: Christi Kelly 214-827-3610 ext x298 ckelly@texasneurology.com
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Principal Investigator: Daragh Heitzman, MD

**Not yet
recruiting**

Methodist Neurological Institute
Houston, Texas, United States

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University of Texas Health Sciences Center

San Antonio, Texas, United States, 78229

Contact: Pam Kittrell 210-450-0524 kittrellp@uthscsa.edu

Principal Investigator: Carlayne Jackson, MD

**Not yet
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United States, Utah

University of Utah

Salt Lake City, Utah, United States

**Not yet
recruiting**

United States, Virginia

University of Virginia Health System

Charlottesville, Virginia, United States

Recruiting

United States, Washington

University of Washington

Seattle, Washington, United States, 98195

Contact: Sharon Downing 206-543-0081

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sdowning@u.washington.edu

**Not yet
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Australia, New South Wales

Prince of Wales Hospital

Randwick, New South Wales, Australia

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**Not yet
recruiting**

Westmead Hospital

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Contact: Kerry Lenton

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Principal Investigator: Steve Vucic, MBBS (Hons I), PhD

Australia, Queensland

Royal Brisbane and Women's Hospital

Herston, Queensland, Australia, 4029

**Not yet
recruiting**

Australia, Victoria

Calvary Health Care Bethlehem

Melbourne, Victoria, Australia, 3121

**Not yet
recruiting**

Contact: Susan Caldwell 613 9595 3355

Belgium

Cliniques Universitaires Saint-Luc Brussels, Belgium	Not yet recruiting
AZ St-Lucas Gent, Belgium	Not yet recruiting
UZ Leuven Leuven, Belgium	Not yet recruiting

Canada

Univ of Calgary / Foothills MC Calgary, Canada	Not yet recruiting
London Health Sciences Centre London, Canada	Not yet recruiting
Mcgill University Montreal, Canada, H3A 2B4 Contact: Jo-Wen Wang 514-398-1779 jo-wen.wang@mcgill.ca Principal Investigator: Angela Genge, MD	Not yet recruiting
CHUM - Hopital Notre Dame Montreal, Canada, H2L 4M1 Contact: Marie Morin 514-890-8000 ext x25434 marie-christine.morin.chum@ssss.gouv.qc.ca Principal Investigator: Genevieve Matte, MD	Not yet recruiting
Sunnybrook and Women's College and Health Sciences Centre Toronto, Canada	Not yet recruiting
University of British Columbia Vancouver, Canada	Not yet recruiting

France

CHRU de Lille - Hôpital Roger Salengro Lille, France	Not yet recruiting
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CHU de Limoges - Hôpital Dupuytren Limoges, France	Not yet recruiting
Centre Hospitalier La Timone Marseille, France	Not yet recruiting
CHU Gui de Chauliac Montpellier, France	Not yet recruiting
CHU de Nice - Hôpital de l'Archet 1 Nice, France	Not yet recruiting
Hôpital La Pitié Salpêtrière Paris, France	Not yet recruiting

Germany

Charité - Universitätsmedizin Berlin Berlin, Germany	Not yet recruiting
Bergmannsheil Gmbh Bochum, Germany	Not yet recruiting
Medizinische Hochschule Hannover (MHH) Hannover, Germany	Not yet recruiting
Universitätsklinikum Jena Jena, Germany	Not yet recruiting
University of Ulm, RKU Ulm, Germany	Not yet recruiting

Ireland

Beaumont Hospital Dublin, Ireland, Dublin 9 Contact: Catherine Lynch 353-1-809-3874 Principal Investigator: Orla Hardiman	Not yet recruiting clynch@rcsi.ie
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Netherlands

Academisch Medisch Centrum	Not yet
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Amsterdam, Netherlands	recruiting
UMC St. Radboud Nijmegen, Netherlands	Not yet recruiting
Universitair Medisch Centrum Utrecht Utrecht, Netherlands	Not yet recruiting
Spain	
Hospital Universitario de Bellvitge Barcelona, Spain	Not yet recruiting
Hospital Vall d'Hebron Barcelona, Spain	Not yet recruiting
Hospital La Paz Madrid, Spain, 28046 Contact: Francisco Rodríguez de Rivera 34917277444 unidadela.lapaz@gmail.com Contact: Ruben Cazorla unidadela.lapaz@gmail.com Principal Investigator: Francisco Rodriguez de Rivera	Not yet recruiting
Hospital Carlos III Madrid, Spain Contact: Jesus Mora Pardina ela.hciiii@salud.madrid.org Contact: Yolanda Moran ela.hciiii@salud.madrid.org Principal Investigator: Jesus Mora Pardina	Not yet recruiting
Sweden	
Sahlgrenska Universitetssjukhuset Göteborg, Sweden	Not yet recruiting
Karolinska Universitetssjukhuset, Solna Stockholm, Sweden	Not yet recruiting
United Kingdom	
Queen Elizabeth Hospital Birmingham, United Kingdom, B15 2TH Contact: Sarah Dhariwal 44-121-627-2085 Sarah.Dhariwal@uhb.nhs.uk	Not yet recruiting

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Principal Investigator: Carolyn Young

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John Radcliffe Hospital

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recruiting**

Sheffield Institute for Transnational Neuroscience

Sheffield, United Kingdom

**Not yet
recruiting**

Sponsors and Collaborators

Biogen Idec

 **More Information**

No publications provided

Responsible Party: Biogen Idec (Medical Director EMPOWER Study)

ClinicalTrials.gov Identifier: [NCT01281189](https://clinicaltrials.gov/ct2/show/study/NCT01281189) [History of Changes](#)

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Keywords provided by Biogen Idec:

Amyotrophic Lateral Sclerosis

ALS

Motor Neurone Disease

Additional relevant MeSH terms:

Amyotrophic Lateral Sclerosis
Sclerosis
Motor Neuron Disease
Spinal Cord Diseases
Central Nervous System Diseases

Nervous System Diseases
Neurodegenerative Diseases
Neuromuscular Diseases
Pathologic Processes

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