GIMBE
EVIDENCE FOR HEALTH

Sperimentazioni Cliniche

Nuove Sfide per i Comitati Etici

Bologna, 7 novembre 2014

Registri di Trial

Cristiana Forni
Istituto Ortopedico Rizzoli

Outline

1. Overview dei registri di trial
2. Come cercare i trial registrati: i meta registri
3. Cosa ci consentono di vedere
4. Focus su un registro di trial

Outline

1. **Overview dei registri di trial**
2. Come cercare i trial registrati: i meta registri
3. Cosa ci consentono di vedere
4. Focus su un registro di trial

MARIO NEGRI
ISTITUTO DI RICERCHE FARMACOLOGICHE

- Home
- The Register
- Glossary
- About Us
- Links
- Ethics committees

Search The Register

This site complies to the HONcode standard for trustworthy health information

Clinical Trials Register

World Health Organization — Who's Internetaional Clinical Trials Registry Platform Search Portal (ICTRP)

European Clinical Trials Database — EudraCT — European Clinical Trials Database (EUdraCT)
I dati pediatrici saranno disponibili a settembre 2010.
Paediatric data will become available in September 2010

ClinicalTrials.gov — ClinicalTrials.gov

ISRCTN REGISTER — International Standard Randomised Controlled Trial Number Register

ANZCTR Australian New Zealand Clinical Trials Registry — Australian New Zealand Clinical Trials Registry(ANZCTR)

ChiCTR 中国临床试验注册中心 Chinese Clinical Trial Registry — Chinese Clinical Trial Register (ChiCTR)

Deutsches Register Klinischer Studien
German Clinical Trials Register — German Clinical Trials Register (DRKS)

CLINICAL TRIALS REGISTRY-INDIA
NATIONAL INSTITUTE OF MEDICAL STATISTICS,(ICMR) — Clinical Trials Registry - India

Coordinator of the register: Department of Public Health

Outline

1. Overview dei registri di trial
2. **Come cercare i trial registrati: i meta registri**
3. Cosa ci consentono di vedere
4. Focus su un registro di trial

Current Controlled Trials

- Trial registration
- Unique identification scheme
- International databases

Welcome to Current Controlled Trials

Current Controlled Trials allows users to search, register and share information about clinical trials. Access to all the information on this site is free; charges for the registration services offered by Current Controlled Trials are available on request. Publication services are also available via the range of open access peer-reviewed journals published by our sister company, BioMed Central.

Search for trials:

- Trials uniquely identified by an ISRCTN
- Search across multiple registers (including the NHS in England and US ClinicalTrials.gov)

Register your trial:

- Apply for a unique identifier - the ISRCTN
- Contact us in order to let us host and search your trial register

Publish your trial:

- Choose BioMed Central's open access peer-reviewed Trials journal
- Select other BioMed Central open access peer-reviewed journals

Latest ISRCTNs assigned (Total: 12936)

29 ottobre 2014: ISRCTN67427351 - Effectiveness of regular weighing and feedback by community midwives in preventing excessive gestational weight gain: randomised controlled trial. (POPS 2)

29 ottobre 2014: ISRCTN95282830 - The ACORN study: Coping and Relaxation in Pregnancy

29 ottobre 2014: ISRCTN40319192 - Adaptive study of IL-2 dose frequency on regulatory T cells in type 1 diabetes (DILfrequency)

Latest papers citing ISRCTNs in PubMed

15 gennaio 2015: *Food Chem.* Effects of functional olive oil enriched with its own phenolic compounds on endothelial function in hypertensive patients. A randomised controlled trial.
[ISRCTN03450153] [PubMed]

23 ottobre 2014: *N. Engl. J. Med.* High-dose rifapentine with moxifloxacin for pulmonary tuberculosis.
[ISRCTN44153044] [PubMed]

07 ottobre 2014: *Trials.* Effects of varenicline and cognitive bias modification on neural response to smoking-related cues: study protocol for a randomized controlled study.
[ISRCTN65690030] [PubMed]

Email updates

Enter your email below to get these and other periodic updates from Current Controlled Trials straight to your inbox.

email address

Sign up

*meta*Register of Controlled Trials (*m*RCT) - active registers

SEARCH FOR	RESULTS ORDER	DIRECTION	MAX RESULTS	ALL REGISTERS	
	Relevance	Descending	10 per page	☐	GO

Those registers which appear below regularly update their records in the *meta*Register of Controlled Trials (at least annually).

- ☐ ISRCTN Register (International) - copy of ISRCTN Register
- ☐ The Wellcome Trust (UK) - subset from ISRCTN Register
- ☐ Action Medical Research (UK) - subset from ISRCTN Register
- ☐ UK trials (UK) - subset from ISRCTN Register, UK trials only
- ☐ NIH ClinicalTrials.gov Register (International) - subset of randomised trial records

Register of Controlled Trials (*m*RCT) - active registers

SEARCH FOR	RESULTS ORDER	DIRECTION	MAX RESULTS	ALL REGISTERS	
pregabalin AND fibromyalgia	Relevanc	Descending	10 per page	☑	GO

Those registers which appear below regularly update the records in the *meta*Register of Controlled Trials (at least annually).

- ☑ ISRCTN Register (International) - copy of ISRCTN Register
- ☑ The Wellcome Trust (UK) - subset from ISRCTN Register
- ☑ Action Medical Research (UK) - subset from ISRCTN Register
- ☑ UK trials (UK) - subset from ISRCTN Register, UK trials only
- ☑ NIH ClinicalTrials.gov Register (International) - subset of randomised trial records

Introduction

Find trials
active registers
mental health register
archived registers
all registers
tips on searching

Information
about mRCT
mRCT FAQs

metaRegister of Controlled Trials (mRCT)

Showing records: **1** to **10** of **41**

SEARCH FOR	RESULTS ORDER	SELECTION	MAX RESULTS	
pregabalin AND fibromyalgia	Relevance	Descending	10 per page	GO

1	Fibromyalgia of Less Than One Year Duration. Study of Pregabalin	
	Status:	Not yet recruiting
	Source of record:	NIH ClinicalTrials.gov Register (International) - subset of randomised trial records
2	Safety and Efficacy Study of Pregabalin in Fibromyalgia	
	Status:	Completed
	Source of record:	NIH ClinicalTrials.gov Register (International) - subset of randomised trial records
3	A Study of the Efficacy and Safety of Pregabalin for the Treatment of Fibromyalgia	
	Status:	Completed
	Source of record:	NIH ClinicalTrials.gov Register (International) - subset of randomised trial records
4	A Phase 3b Multicenter Study of Pregabalin in Fibromyalgia Subjects Who Have Comorbid Depression	
	Status:	Recruiting
	Source of record:	NIH ClinicalTrials.gov Register (International) - subset of randomised trial records
5	Randomized, Double-Blind, Placebo-Controlled Trial Of Pregabalin In Patients With Fibromyalgia.	
	Status:	Completed
	Source of record:	NIH ClinicalTrials.gov Register (International) - subset of randomised trial records
6	An Open-Label Trial of Pregabalin in Patients With Fibromyalgia	
	Status:	Completed

Introduction

Find trials
active registers
mental health register
archived registers
all registers
tips on searching

Information
about *m*RCT
*m*RCT FAQs

[...Back to search results]
[Print-friendly version]

Randomized, Double-Blind, Placebo-Controlled Study Of Pregabalin In Patients With Fibromyalgia

Link to the ClinicalTrials.gov record	Information obtained from ClinicalTrials.gov on February 23, 2012
Title of trial/grant title	Randomized, Double-Blind, Placebo-Controlled Study Of Pregabalin In Patients With Fibromyalgia
Current status of trial	Completed
Sponsors and collaborators	Pfizer
Information provider	Pfizer
ClinicalTrials.gov identifier	NCT00830167
Purpose	This study will compare pregabalin with placebo for the duration of 15 weeks to evaluate the efficacy and safety of pregabalin in patients with fibromyalgia.
Condition(s)	Fibromyalgia
Intervention(s)	Drug: Placebo Drug: Pregabalin
Phase	Phase III
Study type and design	Allocation: Randomized, Endpoint Classification: Safety/Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator), Primary Purpose: Treatment
Official title	Randomized, Double-Blind, Multicenter, Placebo-Controlled Study To Evaluate Efficacy And Safety Of Pregabalinï¼¿CI-1008ï¼¿In The Treatment Of Fibromyalgia
Primary outcome	Numerical rating scale for pain 15 weeks No
Secondary outcome	Patient Global Impression of Change (PGIC) 15 weeks No Medical Outcomes Study - Sleep Scale (MOS-Sleep Scale) 15 weeks No Quality of Sleep Score from the Daily Sleep Diary 15 weeks No Fibromyalgia Impact Questionnaire (FIQ) 15 weeks No Short-Form 36 Health Survey (SF-36) 15 weeks No Pain Visual Analog Scale (Pain VAS) 15 weeks No Assessment of Safety 16 weeks Yes

International Clinical Trials Registry Platform (ICTRP)

The mission of the WHO International Clinical Trials Registry Platform is **to ensure that a complete view of research is accessible to all those involved in health care decision making**. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.

World Health Organization

International Clinical Trials Registry Platform
Search Portal

Home | Advanced Search | List By | Search Tips | UTN | ICTRP website | Contact us

Example: liver cancer OR breast cancer NOT genetic

Search | Search tips

Welcome

- The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
- To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. More information
- Please note: This Search Portal is not a clinical trials registry. How to register a trial
- For mobile users, please use this link http://apps.who.int/trialsearch/ictrpmob.aspx. It can be opened from any smartphone
- It is now possible to export the results of the search into XML. More information
- Crawling the ICTRP database now requires a username/password. To request access to the crawling pages plea send an email to ictrpinfo@who.int
- Call for public Consultation: WHO Statement on Public Disclosure of Clinical Trial Results More information

Data Providers

Data sets fr ata providers are updated every Wednesday ing according to the following schedule:
Every w

- Australian New Zealand Clinical Trials Registry, last data file im ed on **13 October 2014**
- ClinicalTrials.gov, last data file imported on **13 October 2014**
- EU Clinical Trials Register (EU-CTR), last data file imported on **7 Oc er 2014**
- ISRCTN, last data file imported on **13 October 2014**
- The Netherlands National Trial Register, last data file imported on **13 O ber 2014**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **13 Oc er 2014**
- Chinese Clinical Trial Registry, last data file imported on **13 October 201**
- Clinical Trials Registry - India, last data file imported on **13 October 2014**
- Clinical Research Information Service - Republic of Korea, last data file i rted on **13 October 2014**
- Cuban Public Registry of Clinical Trials, last data file imported on **13 Oc er 2014**
- German Clinical Trials Register, last data file imported on **13 October 14**
- Iranian Registry of Clinical Trials, last data file imported on **13 Octob 2014**
- Japan Primary Registries Network, last data file imported on **13 Oc er 2014**
- Pan African Clinical Trial Registry, last data file imported on **16 S tember 2014**
- Sri Lanka Clinical Trials Registry, last data file imported on **13 tober 2014**
- Thai Clinical Trials Register (TCTR), last data file imported o **3 October 2014**

Fields can be left blank. Click on the field name hyperlink for an explanation of each search field

Look for trials with the exact phrase or contains

	Example: liver cancer OR breast cancer	in the Title
AND	Example: Diphtheria NOT tetanus	in the Condition
AND	Example: transplant AND immunosuppressant	in the Intervention

☐ Search for clinical trials in children

Recruitment status is: Recruiting

Primary sponsor is or contains:

Secondary ID is or contains:

Countries of recruitment are:

Afghanistan
Albania
Algeria
American Samoa
Andorra
Angola
Antigua and Barbuda
Argentina

Free Text Country :

>>

<<

Clear

Date of registration is between: dd/mm/yyyy and dd/mm/yyyy

Search Clear Search Tips

World Health Organization

International Clinical Trials Registry Platform
Search Portal

Home | Advanced Search | List By | Search Tips | UTN | ICTRP website | Contact us

pregabalin AND fibromyalgia | Search | Search tips

Welcome

- The Clinical Trials Search Portal provides access to a central database containing the trial registration data sets provided by the registries listed on the right. It also provides links to the full original records.
- To facilitate the unique identification of trials, the Search Portal bridges (groups together) multiple records about the same trial. More information
- Please note: This Search Portal is not a clinical trials registry. How to register a trial
- For mobile users, please use this link http://apps.who.int/trialsearch/ictrpmob.aspx. It can be opened from any smartphone
- It is now possible to export the results of the search into XML. More information
- Crawling the ICTRP database now requires a username/password. To request access to the crawling pages please send an email to ictrpinfo@who.int
- Call for public Consultation: WHO Statement on Public Disclosure of Clinical Trial Results More information

Data Providers

Data sets from data providers are updated every Wednesday evening according to the following schedule:
Every week:

- Australian New Zealand Clinical Trials Registry, last data file imported on **27 October 2014**
- ClinicalTrials.gov, last data file imported on **27 October 2014**
- EU Clinical Trials Register (EU-CTR), last data file imported on **27 October 2014**
- ISRCTN, last data file imported on **27 October 2014**
- The Netherlands National Trial Register, last data file imported on **27 October 2014**

Every 4 weeks:

- Brazilian Clinical Trials Registry (ReBec), last data file imported on **13 October 2014**
- Chinese Clinical Trial Registry, last data file imported on **27 October 2014**
- Clinical Trials Registry - India, last data file imported on **13 October 2014**
- Clinical Research Information Service - Republic of Korea, last data file imported on **13 October 2014**
- Cuban Public Registry of Clinical Trials, last data file imported on **13 October 2014**
- German Clinical Trials Register, last data file imported on **13 October 2014**
- Iranian Registry of Clinical Trials, last data file imported on **13 October 2014**
- Japan Primary Registries Network, last data file imported on **13 October 2014**
- Pan African Clinical Trial Registry, last data file imported on **27 October 2014**
- Sri Lanka Clinical Trials Registry, last data file imported on **13 October 2014**
- Thai Clinical Trials Register (TCTR), last data file imported on **13 October 2014**

World Health Organization

International Clinical Trials Registry Platform Search Portal

Home | Advanced Search | List By | Search Tips | UTN | ICTRP website | Contact us

Back to Search

Export results to XML

54 records for 34 trials found for: pregabalin AND fibromyalgia (What is this?)

Show 10 records per page

1 2 3 4

Recruitment status	Main ID	Public Title	Date of Registration
Not recruiting	NCT02187159	Treatment of Pain Associated With Fibromyalgia	08/07/2014
Not recruiting	NCT02187471	Treatment of Pain Associated With Fibromyalgia	08/07/2014
Not recruiting	NCT02146430	Treatment of Pain Associated With Fibromyalgia	21/05/2014
Not recruiting	NCT01773993	Special Investigation of Pregabalin for Fibromyalgia (Regulatory Post Marketing Commitment Plan)	18/01/2013
Not Recruiting	EUCTR2012-003197-57-BE	Multiple dose Study to evaluate concentration of Lyrica in lactating women	11/10/2012
Not recruiting	NCT01432236	A Phase 3b Multicenter Study of Pregabalin in Fibromyalgia Subjects Who Have Comorbid Depression	08/09/2011
Not recruiting	NCT01397006	Fibromyalgia of Less Than One Year Duration. Study of Pregabalin	15/07/2011
Recruiting	NCT01387607	A Study For Pregabalin In Patients With Fibromyalgia	30/06/2011
Not recruiting	ISRCTN20173707	Combination drug therapy for fibromyalgia pain	28/02/2011
Not recruiting	NCT01280747	Examination of Pregabalin Access for Treatment of Indicated Pain Disorders: the ExPAND Study	19/01/2011

1 2 3 4

54 records for 34 trials found for: pregabalin AND fibromyalgia (What is this?)

Show 10 records per page

1 2 3 4

Recruitment status	Main ID	Public Title	Date of Registration
Not recruiting	NCT02187159	Treatment of Pain Associated With Fibromyalgia	08/07/2014
Not recruiting	NCT02187471	Treatment of Pain Associated With Fibromyalgia	08/07/2014
Not recruiting	NCT02146430	Treatment of Pain Associated With Fibromyalgia	21/05/2014
Not recruiting	NCT01773993	Special Investigation of Pregabalin for Fibromyalgia (Regulatory Post Marketing Commitment Plan)	18/01/2013
Not Recruiting	EUCTR2012-003197-57-BE	Multiple dose Study to evaluate concentration of Lyrica in lactating women	11/10/2012
Not recruiting	NCT01432236	A Phase 3b Multicenter Study of Pregabalin in Fibromyalgia Subjects Who Have Comorbid Depression	08/09/2011
Not recruiting	NCT01397006	Fibromyalgia of Less Than One Year Duration. Study of Pregabalin	15/07/2011
Recruiting	NCT01387607	A Study For Pregabalin In Patients With Fibromyalgia	30/06/2011
Not recruiting	ISRCTN20173707	Combination drug therapy for fibromyalgia pain	28/02/2011
Not recruiting	NCT01280747	Examination of Pregabalin Access for Treatment of Indicated Pain Disorders: the ExPAND Study	19/01/2011

Recruitment status	Main ID	Public title	Date of registration
Authorised	EUCTR2011-002480-19-ES	In this fibromyalgia pain study in patients taking medication for depression, neither subjects nor investigators will know treatment assignments. The study is to determine if pregabalin demonstrates improvement compared to placebo (inactive substance)in improving pain associated with fibromyalgia. Subjects will be randomly assigned by chance(like the flip of a coin) to receive either pregabalin or placebo in one treatment period and then switch to the opposite for the second treatment period.	17/11/2011
Not Recruiting	EUCTR2011-002480-19-IT	The study objective is to determine if pregabalin demonstrates improvement compared to placebo in improving pain associated with fibromyalgia. Neither subjects nor investigators will know treatment assignments. Subjects will be randomly assigned by chance to receive either pregabalin or placebo in one treatment period and then switch to the opposite for the second treatment period.	23/07/2012

Main

Note: This record shows only the 20 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	21 July 2014
Main ID:	NCT02187159
Date of registration:	08/07/2014
Primary sponsor:	Daiichi Sankyo Inc.
Public title:	Treatment of Pain Associated With Fibromyalgia
Scientific title:	A Randomized, Double-Blind, Placebo- and Active-Controlled Study of DS-5565 for Treatment of Pain Associated With Fibromyalgia
Date of first enrolment:	July 2014
Target sample size:	1200
Recruitment status:	Not yet recruiting
URL:	http://clinicaltrials.gov/show/NCT02187159
Study type:	Interventional
Study design:	Allocation: Randomized, Endpoint Classification: Safety/Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Primary Purpose: Treatment

Countries of recruitment

Contacts

Name:	INC Research	**Name:**	Domenico Merante, MD
Address:		**Address:**	
Telephone:		**Telephone:**	
Email:	SM_DS5565_FM_Info@incresearch.com	**Email:**	
Affiliation:		**Affiliation:**	Daiichi Sankyo Inc.

Key inclusion & exclusion criteria

Outline

1. Overview dei registri di trial
2. Come cercare i trial registrati: i meta registri
3. **Cosa ci consentono di vedere**
4. Focus su un registro di trial

Randomized, Double-Blind, Placebo-Controlled Trial Of Pregabalin In Patients With Fibromyalgia.

This study has been completed.

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT00333866

First received: June 2, 2006
Last updated: April 25, 2013
Last verified: March 2009
History of Changes

Purpose

This study, will compare pregabalin with placebo for the duration of 14 weeks to evaluate the efficacy and safety of pregabalin in patients with fibromyalgia.

Condition	Intervention	Phase
Fibromyalgia	Drug: pregabalin	Phase 3

This study has been completed.

Sponsor:
Pfizer

Information provided by (Responsible Party):
Pfizer

ClinicalTrials.gov Identifier:
NCT00333866

First received: June 2, 2006
Last updated: April 25, 2013
Last verified: March 2009
History of Changes

Results First Received: November 20, 2008

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double-Blind; Primary Purpose: Treatment
Condition:	Fibromyalgia
Interventions:	Drug: pregabalin Drug: placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations

Recruitment from 73 centers in North America [Canada (12) and Mexico (4)], South America [Venezuela (3)], Europe [Denmark (2), France (5), Germany (5), Italy (6), Netherlands (5), Portugal (4), Spain (4), Sweden (4), Switzerland (3) and United Kingdom(5)] and Asia [India (4) and Korea (3)] and Australia (4).

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double-Blind; Primary Purpose: Treatment
Condition:	Fibromyalgia
Interventions:	Drug: pregabalin Drug: placebo

Participant Flow

Show Participant Flow

Baseline Characteristics

Show Baseline Characteristics

Outcome Measures

Show All Outcome Measures

1. Primary: Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

Show Outcome Measure 1

2. Primary: Patient Global Impression of Change (PGIC) [Time Frame: Week 14]

Show Outcome Measure 2

3. Secondary: Change From Baseline in Mean Sleep Quality Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

Show Outcome Measure 3

3. Secondary: Change From Baseline in Mean Sleep Quality Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

Show Outcome Measure 3

4. Secondary: Change From Baseline in Weekly Mean Sleep Quality Score [Time Frame: Baseline, Week 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14]

Show Outcome Measure 4

5. Secondary: Percentage of Participants With Optimal Sleep Assessed Using MOS-SS [Time Frame: Baseline, Week 14]

Show Outcome Measure 5

6. Secondary: Change From Baseline in Medical Outcomes Study (MOS): Sub-scales at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 6

7. Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Subscale Scores at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 7

8. Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Total Scores at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 8

9. Secondary: Change From Baseline in Short Form-36 (SF-36) Health Survey at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 9

10. Secondary: Change From Baseline in Multidimensional Assessment of Fatigue (MAF) at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 10

11. Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 11

12. Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 12

13. Secondary: Total Daily Acetaminophen Dose [Time Frame: Week 14]

Show Outcome Measure 11

12. Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]

Show Outcome Measure 12

13. Secondary: Total Daily Acetaminophen Dose [Time Frame: Week 14]

Show Outcome Measure 13

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Show Limitations and Caveats

More Information

Show More Information

TO TOP

For Patients & Families | For Researchers | For Study Record Managers

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Recruitment from 73 centers in North America [Canada (12) and Mexico (4)], South America [Venezuela (3)], Europe [Denmark (2), France (5), Germany (5), Italy (6), Netherlands (5), Portugal (4), Spain (4), Sweden (4), Switzerland (3) and United Kingdom(5)] and Asia [India (4) and Korea (3)] and Australia (4).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	Placebo matched to pregabalin capsules orally twice daily up to Week 14.
Pregabalin 300 mg	Pregabalin capsule 150 milligram (mg) orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily and Day 4 onwards: 150 mg orally twice daily fixed dose up to Week 14.
Pregabalin 450 mg	Pregabalin capsule 225 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12 onwards: 225 mg orally twice daily fixed dose up to Week 14.
Pregabalin 600 mg	Pregabalin capsule 300 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12-14: 225 mg orally twice daily and then 300 mg orally twice daily fixed dose up to Week 14.

Participant Flow: Overall Study

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
STARTED	189	187	184	187
TREATED	184	184	182	186
COMPLETED	141	122	122	121

Participant Flow: Overall Study

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
STARTED	189	187	184	187
TREATED	184	184	182	186
COMPLETED	141	123	133	121
NOT COMPLETED	48	64	51	66
Adverse Event	23	37	38	47
Unspecified	3	2	2	2
Lack of Efficacy	8	6	3	5
Lost to Follow-up	1	2	2	2
Withdrawal by Subject	8	14	4	9
Randomized but not Treated	5	3	2	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study medication, regardless of medication compliance.

Total	Total of all reporting groups

Baseline Measures

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg	Total
Number of Participants [units: participants]	184	184	182	186	736
Age [units: years] Mean ± Standard Deviation	48.1 ± 11.3	48.4 ± 10.8	48.0 ± 11.3	49.6 ± 11.3	48.5 ± 11.2
Gender [units: participants]					
Female	168	167	169	169	673
Male	16	17	13	17	63
Mean Pain Score [1] [units: Units on a scale] Mean ± Standard Deviation	6.68 ± 1.48	6.76 ± 1.29	6.57 ± 1.31	6.59 ± 1.37	6.65 ± 1.36
Mean Sleep Quality Score [2] [units: Units on a scale] Mean ± Standard Deviation	6.01 ± 1.90	5.94 ± 1.70	5.94 ± 1.70	5.91 ± 1.80	5.95 ± 1.77
Percentage of Participants With Optimal Sleep Assessed Using MOS-SS [3] [units: Percentage of Participants]	20.33	25.27	24.57	17.03	87.2
Medical Outcome Study Sleep Scale (MOS-SS) [4] [units: Units on a scale] Mean ± Standard Deviation					
	60.02				60.47

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

Measure Type	Primary
Measure Title	Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14)
Measure Description	Daily pain diary consists of 11-point NRS ranging from 0(no pain) to 10(worst possible pain). Participants rated their pain during past 24 hours, self-assessment done daily at awakening. Baseline=Last 7 available pain scores before taking study medication up to and including Day 1. Final weekly (endpoint) mean pain score is defined as the mean pain score from the last 7 pain diary entries in the study while the participant was on study medication.
Time Frame	Baseline, Week 14
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full Analysis Set (FAS) included all randomized participants who received at least 1 dose of study medication, regardless of medication compliance. Missing data were imputed using last observation carried forward (LOCF) method. 'N' (number of participants analyzed) signifies participants evaluable for this measure.

Reporting Groups

	Description
Placebo	Placebo matched to pregabalin capsules orally twice daily up to Week 14.
Pregabalin 300 mg	Pregabalin capsule 150 milligram (mg) orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily and Day 4 onwards: 150 mg orally twice daily fixed dose up to Week 14.
Pregabalin 450 mg	Pregabalin capsule 225 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12 onwards: 225 mg orally twice daily fixed dose up to Week 14.

	twice daily and Day 12-14: 225 mg orally twice daily and then 300 mg orally twice daily fixed dose up to Week 14.

Measured Values

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Number of Participants Analyzed [units: participants]	184	184	181	186
Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [units: Units on a scale] Least Squares Mean ± Standard Error	-0.73 ± 0.14	-1.06 ± 0.14	-1.29 ± 0.14	-0.96 ± 0.14

Statistical Analysis 1 for Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14)

Groups [1]	Placebo vs. Pregabalin 600 mg
Method [2]	ANCOVA
P Value [3]	0.2361
Least Squares (LS) mean difference [4]	-0.23
95% Confidence Interval	(-0.61 to 0.15)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	P value was calculated using Analysis of Covariance (ANCOVA) with treatment and center in the model, and the baseline mean pain score as covariate.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Hochberg's approach was used to protect the Type I error rate at 0.05 level, Hochberg adjusted p-values were presented.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.

Pregabalin 600 mg	Pregabalin capsule 300 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12-14: 225 mg orally twice daily and then 300 mg orally twice daily fixed dose up to Week 14.

Measured Values

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Number of Participants Analyzed [units: participants]	183	179	174	178
Change From Baseline in Weekly Mean Sleep Quality Score [units: Units on a scale] Least Squares Mean ± Standard Error				
Week 1 (n=183,179,174,178)	-0.38 ± 0.14	-1.20 ± 0.15	-1.08 ± 0.15	-1.23 ± 0.15
Week 2 (n=180,172,168,174)	-0.62 ± 0.14	-1.48 ± 0.15	-1.43 ± 0.15	-1.59 ± 0.15
Week 3 (n=174, 164, 159,163)	-0.75 ± 0.15	-1.42 ± 0.15	-1.56 ± 0.15	-1.90 ± 0.15
Week 4 (n=165,157,155,156)	-0.73 ± 0.15	-1.52 ± 0.15	-1.67 ± 0.15	-2.01 ± 0.15
Week 5 (n=163, 150, 152,148)	-0.82 ± 0.15	-1.67 ± 0.15	-1.69 ± 0.15	-1.99 ± 0.15
Week 6 (n=159,145,148,144)	-0.84 ± 0.15	-1.56 ± 0.15	-1.76 ± 0.16	-2.15 ± 0.16
Week 7 (n=155,140,144,133)	-0.91 ± 0.15	-1.50 ± 0.16	-1.83 ± 0.16	-2.20 ± 0.16
Week 8 (n=149,133,142,127)	-0.99 ± 0.15	-1.60 ± 0.16	-1.95 ± 0.16	-2.25 ± 0.16
Week 9 (n=146,128,141,126)	-1.11 ± 0.15	-1.64 ± 0.16	-1.94 ± 0.16	-2.24 ± 0.16
Week 10 (n=144,125,139,126)	-1.14 ± 0.16	-1.75 ± 0.16	-2.03 ± 0.16	-2.34 ± 0.17
Week 11 (n=143,123,137,121)	-1.09 ± 0.16	-1.65 ± 0.17	-1.92 ± 0.16	-2.24 ± 0.17
Week 12 (n=141,121,135,119)	-1.22 ± 0.16	-1.62 ± 0.17	-1.95 ± 0.16	-2.29 ± 0.17
Week 13 (n=140,120,133,118)	-1.05 ± 0.16	-1.66 ± 0.17	-1.93 ± 0.17	-2.26 ± 0.17
Week 14 (n=134,115,128,111)	-1.08 ± 0.16	-1.73 ± 0.17	-1.95 ± 0.17	-2.29 ± 0.18

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Reporting Groups

	Description
Placebo	Placebo matched to pregabalin capsules orally twice daily up to Week 14.
Pregabalin 300 mg	Pregabalin capsule 150 milligram (mg) orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily and Day 4 onwards: 150 mg orally twice daily fixed dose up to Week 14.
Pregabalin 450 mg	Pregabalin capsule 225 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12 onwards: 225 mg orally twice daily fixed dose up to Week 14.
Pregabalin 600 mg	Pregabalin capsule 300 mg orally twice daily following a 2 week titration phase, Day 1-3: 75 mg orally twice daily, Day 4-8: 150 mg orally twice daily, Day 9-11: 200 mg orally twice daily and Day 12-14: 225 mg orally twice daily and then 300 mg orally twice daily fixed dose up to Week 14.

Serious Adverse Events

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Total, serious adverse events				
# participants affected / at risk	4/184 (2.17%)	2/184 (1.09%)	8/182 (4.40%)	4/186 (2.15%)
Blood and lymphatic system disorders				

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: Pfizer has the right to review disclosures, requesting a delay of <60 days. Investigator will postpone single center publications until after disclosure of pooled data (all sites), <12 mo from study completion/termination at all participating sites. Investigator may not disclose previously undisclosed confidential info other than study results.

Results Point of Contact:

Name/Title: Pfizer ClinicalTrials.gov Call Center

Outline

1. Overview dei registri di trial
2. Come cercare i trial registrati: i meta registri
3. Cosa ci consentono di vedere
4. **Focus su un registro di trial**

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.

ClinicalTrials.gov currently lists 177,688 studies with locations in all 50 states and in 187 countries.

Text Size

Search for Studies

Example: "Heart attack" AND "Los Angeles"

Search

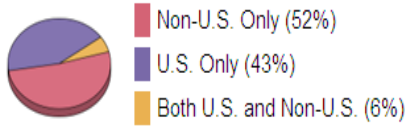
Advanced Search | See Studies by Topic

See Studies on a Map

Search Help

- How to search
- How to find results of studies
- How to read a study record

Locations of Recruiting Studies



Total N = 34,171 studies
Data as of October 29, 2014

- See more trends, charts, and maps

For Patients & Families

- How to find studies
- See studies by topic
- Learn about clinical studies
- Learn more...

For Researchers

- How to submit studies
- Download content for analysis
- About the results database
- Learn more...

For Study Record Managers

- Why register?
- How to register study records
- FDAAA 801 Requirements
- Learn more...

Learn More

- ClinicalTrials.gov Online Training
- Glossary of common site terms

For the Press

Using our RSS Feeds

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

Organization:

One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: Forgot password

Login

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.

Send email to ClinicalTrials.gov PRS Administration

Organization: IORizzoli Username: cforni Email: cristiana.forni@ior.it [Update] Help us improve: PRS Survey

Records

- New Record
- Edit Record
- View Record
- PRS Review Comments
- **Problems: cforni Records**
- Undelete Record

User Account

- Change Password
- Update User Information
- List IORizzoli Administrator(s)

Help

- **Quick Start Guide**
- What's New Nov 5, 2014
- Protocol Data Entry
- Results Data Entry
- PRS User's Guide

XML Upload

- Upload Records
- Check Upload Status
- Upload from NCI CTRP

Record List - Edit

KEY: PR Pending PRS Review R Contains Results DR Has Delayed Results U Last modified via XML Upload
NP No longer public

	Sort by Protocol ID	ClinicalTrials.gov ID	Sort by Brief Title	Overall Status	Sort by Owner	Responsible Party	Sort by Updater	Sort by Updated	Record Status
Edit	0008363	NCT01602965	Effectiveness Between Nutritional Counseling Monthly Phone Call Versus Self Help Informative Booklet	Recruiting	cforni	[Sponsor]	ARizzi	06/10/2014 06:12	Public
Edit	0013483	NCT01391000	Laser CO2 Versus TENS After Reconstruction of the Rotator Cuff	Completed	cforni	[Sponsor]	ARizzi	10/01/2014 03:59	Public