

## Registri di Trial

**Cristiana Forni**  
Istituto Ortopedico Rizzoli

## Outline

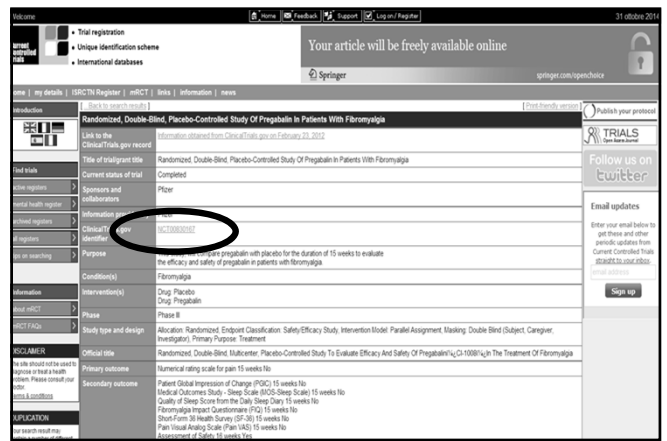
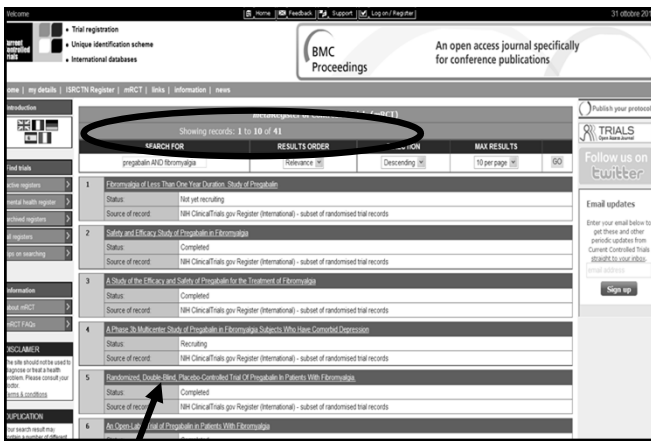
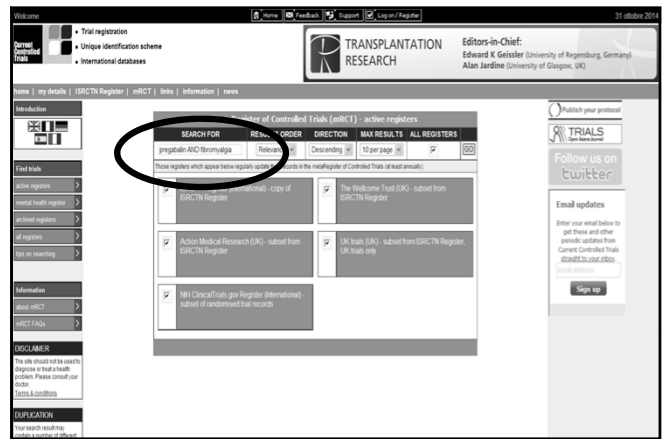
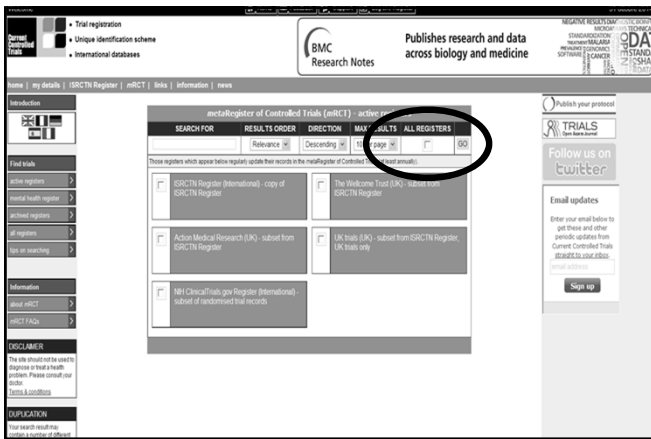
1. Overview dei registri di trial
2. Come cercare i trial registrati: i meta registri
3. Cosa ci consentono di vedere
4. Focus su un registro di trial

## 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

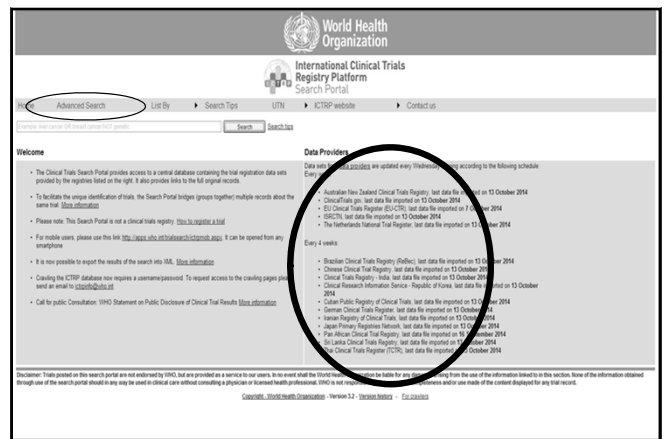
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## International Clinical Trials Registry Platform (ICTRP)

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.



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Look for trials with the exact phrase or contains

Example: liver cancer OR breast cancer

Example: Dexamethasone 1671 tablets

Example: tramadol AND tramadolopressant

Search for  in the Title

AND  in the Condition

AND  in the Intervention

Search for  in the Eligibility

Recruitment status is

Primary sponsor is or contains

Secondary sponsor is or contains

Countries of recruitment are

Free Text Country:

Date of registration is between  and

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Welcome

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:

- Beijing Clinical Trials Registry (BeCTR), last data file imported on 13 October 2014
- Chinese Clinical Trial Registry, last data file imported on 13 October 2014
- Chinese Clinical Trial Register, last data file imported on 13 October 2014
- Clinical Research Information Service - Republic of Korea, last data file imported on 13 October 2014
- Colombian 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 Registry Network, last data file imported on 13 October 2014
- Pan African Clinical Trial Registry, last data file imported on 27 October 2014
- UK Clinical Trials Register, last data file imported on 13 October 2014
- The Clinical Trials Registry (CTR), last data file imported on 13 October 2014

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54 records for 34 trials found for pregabalin AND fibroalgia (abstract)

1224

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	EUC170019-20019F-23-EE	Multiple dose Study to evaluate concentration of Lofexidine in lactating women	11/10/2012
Not recruiting	NCT01432236	A Phase 3a Multicenter Study of Pregabalin in Fibromyalgia Subjects Who Have Comorbid Depression	08/09/2011
Not recruiting	NCT01393906	Efficacy of Less Than One Year Duration Study of Pregabalin	15/07/2011
Recruiting	NCT01181767	A Study For Pregabalin In Patients With Fibromyalgia	30/06/2011
Not recruiting	ISRCTN0173707	Combination drug therapy for fibromyalgia pain	28/02/2011
Not recruiting	NCT01280747	Examination of Pregabalin Access for Treatment of Indicated Pain Disorders: the EuPAND Study	19/01/2011

1224

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Note: This record shows only the 30 statements 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: 27 July 2014

Main ID: NCT01181767

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 enrollment: July 2014

Target sample size: 1200

Recruitment status: Not yet recruiting

URL: <http://clinicaltrials.gov/show/study/NCT01181767>

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	Address: [Redacted]	Name: Domenico Merante, MD	Address: [Redacted]
Telephone: [Redacted]	Address: [Redacted]	Telephone: [Redacted]	Address: [Redacted]
Email: SU_065565_FM_info@incresearch.com	Address: [Redacted]	Email: [Redacted]	Address: [Redacted]
Attention: [Redacted]	Address: [Redacted]	Attention: Daiichi Sankyo Inc	Address: [Redacted]

Key inclusion & exclusion criteria

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Trial record 30 of 40724 for: (NOT NOTEX) CITATIONS  
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### 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

This study has been completed.

**ClinicalTrials.gov Identifier:**  
NCT00333866

**Sponsor:**  
Pfizer

**Information provided by (Responsible Party):**  
Pfizer

First received: June 2, 2006  
 Last updated: April 25, 2013  
 Last verified: March 2009  
[History of Changes](#)

Results First Received: November 20, 2008

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

**► 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 [1]), 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].

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

**► Participant Flow**

**► Baseline Characteristics**

**► Outcome Measures**

- Primary: Change From Baseline in Mean Pain Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]
- Primary: Patient Global Impression of Change (PGIC) [Time Frame: Week 14]
- Secondary: Change From Baseline in Mean Sleep Quality Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]

- Secondary: Change From Baseline in Mean Sleep Quality Score at Endpoint (Up to Week 14) [Time Frame: Baseline, Week 14]
- 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]
- Secondary: Percentage of Participants With Optimal Sleep Assessed Using MOS-SS [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Medical Outcomes Study (MOS) Sub-scales at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Subscale Scores at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Fibromyalgia Impact Questionnaire (FIQ) Total Scores at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Short-Form-36 (SF-36) Health Survey at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Multidimensional Assessment of Fatigue (MAF) at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Hospital Anxiety and Depression Scale (HADS) at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Total Daily Acetaminophen Dose [Time Frame: Week 14]

- Secondary: Change From Baseline in Pain Visual Analogue Scale (VAS) Scores at Week 14 [Time Frame: Baseline, Week 14]
- Secondary: Total Daily Acetaminophen Dose [Time Frame: Week 14]

**► Serious Adverse Events**

**► Other Adverse Events**

**► Limitations and Caveats**

**► More Information**

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**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 [1]), 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**

Reporting Group	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 onward: 150 mg orally twice daily fed 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 12-14: 225 mg orally twice daily fed 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 fed 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

**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.

**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	48.6 ± 11.3	48.5 ± 11.2
Gender [units: participants]					
Female	168	167	169	169	673
Male	16	17	13	17	63
Mean Pain Score <sup>[1]</sup> [units: Units on a scale] Mean ± Standard Deviation	6.68 ± 1.48	6.76 ± 1.29	6.57 ± 1.31	6.59 ± 1.37	6.85 ± 1.36
Mean Sleep Quality Score <sup>[2]</sup> [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 <sup>[3]</sup> [units: Percentage of Participants]	20.33	25.27	24.57	17.03	87.2
Medical Outcome Study Sleep Scale (MOS-SS) <sup>[4]</sup> [units: Units on a scale] Mean ± Standard Deviation					

**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 evening. 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 available for this measure.

**Reporting Groups**

Group	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.

**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 <sup>[1]</sup>	Placebo vs. Pregabalin 600 mg
Method <sup>[2]</sup>	ANCOVA
P Value <sup>[3]</sup>	0.2361
Least Squares (LS) mean difference <sup>[4]</sup>	-0.23
95% Confidence Interval	(-0.81 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 test 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 test 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**

Group	Description
Placebo	Placebo matched to pregabalin capsules orally twice daily up to Week 14.
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**Serious Adverse Events**

	Placebo	Pregabalin 300 mg	Pregabalin 450 mg	Pregabalin 600 mg
Total, serious adverse events				
# serious 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

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- How to read a study record

**Locations of Recruiting Studies**

Non-U.S. Only (2%)  
U.S. Only (4%)  
Both U.S. and Non-U.S. (94%)

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

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EXPIRATION DATE: 08 31 2015  
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- Edit Record
- View Record
- PRS Review Comments
- Problems, Admin Records
- Update Record

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- Quick Start Guide
- What's New: Nov 4, 2014
- Protocol Data Entry
- Results Data Entry
- PRS User's Guide

**XML Upload**

- Upload Records
- Check Upload Status
- Upload from NCI/CIOP

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KEY: PR Pending PRS Review [X] Contains Results [X] Has Delayed Results [X] Last modified via XML Upload [X] No longer public

Study Protocol ID	ClinicalTrials.gov ID	Study Brief Title	Overall Status	Study Owner	Responsible Party	Study Update	Study Updated	Record Status
Edit 000393	NCT01902965	Effectiveness Between Nutritional Counseling Monthly Phone Call Versus Self Help Informative Booklet	Recruiting	clm1	[Sponsor]	ARZ01	06/10/2014 06:12	Public
Edit 001340	NCT01361000	Laser CO2 Versus TENS After Reconstruction of the Rotator Cuff	Completed	clm1	[Sponsor]	ARZ01	10/01/2014 03:59	Public

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