

Table 1. Randomized controlled trials of pregabalin in patients with pDPN completed prior to December 26, 2007.

Protocol	NCT ID	LSLV	Study Title	Publication(s)
1008014	NA	2000	A DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF PREGABALIN FOR TREATMENT OF PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Richter RW, Portenoy R, Sharma U, et al. Relief of painful diabetic peripheral neuropathy with pregabalin: a randomized, placebo-controlled trial. <i>J Pain</i> 2005;6:253–260.
1008029	NA	2000	A 5-WEEK DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF 3 DOSAGES OF PREGABALIN (75, 300 AND 600 MG/DAY) FOR TREATMENT OF PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Lesser H, Sharma U, LaMoreaux L, et al. Pregabalin relieves symptoms of painful diabetic neuropathy: a randomized controlled trial. <i>Neurology</i> 2004;63:2104–2110.
1008131	NA	2000	AN 8 WEEK, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL OF PREGABALIN (300 MG/DAY) FOR RELIEF OF PAIN IN PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Rosenstock J, Tuchman M, LaMoreaux L, et al. Pregabalin for the treatment of painful diabetic peripheral neuropathy: a double-blind, placebo-controlled trial. <i>Pain</i> 2004;110:628–638.
1008040	NA	2001	A PLACEBO-CONTROLLED TRIAL OF PREGABALIN AND AMITRIPTYLINE FOR TREATMENT OF PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Freeman R, Emir B, Parsons B. Predictors of placebo response in peripheral neuropathic pain - insights from pregabalin clinical trials. <i>J Pain Res</i> 2015;8:257-268. Parsons B, Li C. The efficacy of pregabalin in patients with moderate and severe pain due to diabetic peripheral neuropathy. <i>Curr Med Res Opi</i> . 2016;32:929-937. Freynhagen R, Serpell M, Emir B, et al. A comprehensive drug safety evaluation of pregabalin in peripheral neuropathic pain. <i>Pain Pract</i> 2015;15:47-57.
1008173	NA	2001	A 12-WEEK, RANDOMIZED, DOUBLE-BLIND, MULTICENTER, PLACEBO-CONTROLLED STUDY OF PREGABALIN TWICE A DAY (BID) FOR RELIEF OF PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY.	Freynhagen R, Serpell M, Emir B, et al. A comprehensive drug safety evaluation of pregabalin in peripheral neuropathic pain. <i>Pain Pract</i> 2015;15:47-57.
1008149	NA	2002	A 12-WEEK, RANDOMIZED, DOUBLE-BLIND, MULTICENTER, PLACEBO-CONTROLLED STUDY OF PREGABALIN TWICE A DAY (BID) FOR RELIEF OF PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY	Tölle T, Freynhagen R, Versavel M, et al. Pregabalin for relief of neuropathic pain associated with diabetic neuropathy: a randomized, double-blind study. <i>Eur J Pain</i> 2008;12:203–213.
A0081049	NA	2002	EFFICACY AND SAFETY OF PREGABALIN USING AN INDIVIDUAL OPTIMAL TWICE A DAY (BID) DOSE SCHEDULE IN PATIENTS WITH CHRONIC NEUROPATHIC PAIN	Freynhagen R, Strojek K, Griesing T, et al. Efficacy of pregabalin in neuropathic pain evaluated in a 12-week, randomised, double-blind, multicentre, placebocontrolled trial of flexible- and fixed-dose regimens. <i>Pain</i> 2005;115:254–263.
A0081060	NCT0015 9679	2005	A 13-WEEK, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE 4 TRIAL OF PREGABALIN (CI-1008, 600 MG/DAY) FOR RELIEF OF PAIN IN SUBJECTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Arezzo JC, Rosenstock J, Lamoreaux L, et al. Efficacy and safety of pregabalin 600 mg/d for treating painful diabetic peripheral neuropathy: a double-blind placebo controlled trial. <i>BMC Neurol</i> 2008;8:33.
A0081030	NCT0015 6078	2006	A 14-WEEK, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF PREGABALIN (150MG-600MG/DAY) USING A FLEXIBLE OPTIMAL DOSE SCHEDULE IN PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY (DPN).	Freeman R, Emir B, Parsons B. Predictors of placebo response in peripheral neuropathic pain - insights from pregabalin clinical trials. <i>J Pain Res</i> 2015;8:257-268. Parsons B, Li C. The efficacy of pregabalin in patients with moderate and severe pain due to diabetic peripheral neuropathy. <i>Curr Med Res Opin</i> 2016;32:929-937. Freynhagen R, Serpell M, Emir B, et al. A comprehensive drug safety evaluation of pregabalin in peripheral neuropathic pain. <i>Pain Pract</i> 2015;15:47-57.
A0081037	NCT0014 1219	2007	AN 10-WEEK, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE EFFICACY AND SAFETY OF PREGABALIN (150MG-600MG/DAY) USING A FLEXIBLE, OPTIMIZED DOSE SCHEDULE IN SUBJECTS WITH PERIPHERAL NEUROPATHIC PAIN	Moon DE, Lee DI, Lee SC, et al. Efficacy and tolerability of pregabalin using a flexible, optimized dose schedule in Korean patients with peripheral neuropathic pain: a 10-week, randomized, double-blind, placebo-controlled, multicenter study. <i>Clin Ther</i> 2010;32:2370-2385
A0081071	NCT0014 3156	2007	A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL-GROUP, MULTICENTER TRIAL OF PREGABALIN VERSUS PLACEBO IN THE TREATMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY	Freeman R, Emir B, Parsons B. Predictors of placebo response in peripheral neuropathic pain - insights from pregabalin clinical trials. <i>J Pain Res</i> 2015;8:257-268. Parsons B, Li C. The efficacy of pregabalin in patients with moderate and severe pain due to diabetic peripheral neuropathy. <i>Curr Med Res Opin</i> 2016;32:929-937. Freynhagen R, Serpell M, Emir B, et al. A comprehensive drug safety evaluation of pregabalin in peripheral neuropathic pain. <i>Pain Pract</i> 2015;15:47-57.
A0081081	NCT0030 1223	2007	AN 8 WEEK MULTI-CENTER, RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY	Guan Y, Ding X, Cheng Y, et al. Efficacy of Pregabalin for Peripheral Neuropathic Pain: Results of an 8-week, Double-

			TO EVALUATE THE EFFICACY, SAFETY AND TOLERABILITY OF PREGABALIN (150MG-600MG/DAY) USING A FLEXIBLE DOSING SCHEDULE IN THE TREATMENT OF SUBJECTS WITH SYMPTOMS OF NEUROPATHIC PAIN	blind, Placebo-controlled Study Conducted in China. Clin Ther 2011;33:159-166.
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NCT ID = Clinicaltrials.gov registry number; LSLV = last subject last visit

Table 2. Randomized controlled trials of pregabalin in patients with pDPN initiated since September 27, 2007.

Protocol	NCT ID	LSLV	Study Title	Publication(s)
A0081084	NCT00219544	2008	A RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF THE EFFICACY AND SAFETY OF PREGABALIN IN THE TREATMENT OF SUBJECTS WITH PERIPHERAL NEUROPATHIC PAIN	Gilron I, Wajsbrot D, Therrien F, Lemay J. Pregabalin for Peripheral Neuropathic Pain: A Multicenter, Enriched Enrollment Randomized Withdrawal Placebo-controlled Trial. Clin J Pain 2011;27:185-193.
A0081163	NCT00553475	2009	RANDOMIZED, DOUBLE-BLIND, MULTICENTER, PLACEBO-CONTROLLED STUDY TO EVALUATE EFFICACY AND SAFETY OF PREGABALIN (CI-1008) IN THE TREATMENT FOR PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY	Satoh J, Yagihashi S, Baba M, et al. Efficacy and safety of pregabalin for treating neuropathic pain associated with diabetic peripheral neuropathy: a 14 week, randomized, double-blind, placebo-controlled trial. Diabet Med 2011;28:109-116.
A0081242	NCT01057693	2012	A PHASE 3B MULTICENTER, DOUBLE-BLIND, RANDOMIZED WITHDRAWAL EFFICACY AND SAFETY STUDY OF PREGABALIN IN THE TREATMENT OF PATIENTS WITH INADEQUATELY TREATED PAINFUL DIABETIC PERIPHERAL NEUROPATHY	Raskin P, Huffman C, Toth C, et al. Pregabalin in Patients with Inadequately Treated Painful Diabetic Peripheral Neuropathy: A Randomized Withdrawal Trial. Clin J Pain 2014;30:379-390.
A0081268	NCT01455415	2013	A STUDY OF PREGABALIN IN THE TREATMENT OF SUBJECTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY WITH BACKGROUND TREATMENT OF NSAID FOR OTHER PAIN CONDITIONS	Raskin P, Huffman C, Yurkewicz L, et al. Pregabalin in subjects with painful diabetic peripheral neuropathy using an NSAID for other pain conditions: a double-blind crossover study. Clin J Pain 2016;32:203-210.
A0081269	NCT01474772	2013	A PHASE 3B MULTICENTER, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED CROSS-OVER EFFICACY AND SAFETY STUDY OF PREGABALIN IN THE TREATMENT OF PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY AND PAIN ON WALKING	Huffman C, Stacey B, Tuchman M, et al. Efficacy and safety of pregabalin in the treatment of patients with painful diabetic peripheral neuropathy and pain on walking. Clin J Pain 2015;31:946-958.
A0081265	NCT01332149	2014	AN 11-WEEK RANDOMIZED, DOUBLE-BLIND, MULTI CENTER, PLACEBO-CONTROLLED STUDY TO EVALUATE THE EFFICACY, SAFETY AND TOLERABILITY OF PREGABALIN (300 MG/DAY) USING A FIXED DOSING SCHEDULE IN THE TREATMENT OF SUBJECTS S WITH PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY.	Manuscript under revision

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