

CLINICAL TRIALS UPDATE: LOW BACK PAIN*

Description	Interventions	Design	Sponsors/Funding	Location/Contact	NCT ID No.
Study to determine the relative clinical effectiveness of chiropractic care and supervised exercise versus supervised exercise in adolescents with subacute recurrent, or chronic low back pain	Manual spinal manipulation and mobilization plus supervised exercise vs. supervised exercise alone	Randomized, single-blind, active-controlled, parallel assignment	Northwestern Health Sciences University; Health Resources and Services Administration; University of Western States	Two sites; Gert Bronfort, D.C., Ph.D., 952-885-5413, gbronfort@nwhealth.edu	NCT01096628
Study to determine whether a novel placebo for comparison to spinal manipulation is believable and creates a similar expectation for treatment effectiveness as the studied spinal manipulation technique in patients with low back pain	Spinal manipulation technique vs. sham spinal manipulation technique vs. no intervention	Randomized, single-blind, active-controlled, parallel assignment	University of Florida	Joel E. Bialosky, Ph.D., 352-273-8636, bialosky@phhp.ufl.edu	NCT01168999
Study to assess the effects of high-velocity low-amplitude spinal manipulation and low-velocity variable-amplitude spinal manipulation on three types of sensorimotor abilities in patients with acute, subacute, or chronic low back pain	High-velocity low-amplitude lumbopelvic manipulation vs. low-velocity variable-amplitude lumbopelvic manipulation vs. light effleurage and a sham mechanically assisted chiropractic treatment	Randomized, double-blind, placebo-controlled, parallel assignment	Palmer College of Chiropractic; National Center for Complementary and Alternative Medicine	Christine M. Goertz, D.C., Ph.D., 563-884-5159, christine.choate@palmer.edu	NCT00830596
Study to evaluate how Nucynta (tapentadol) immediate release compares with oxycodone immediate release in the treatment of patients with acute low back pain who also have associated leg pain that radiates below the knee	Nucynta (tapentadol) immediate release vs. oxycodone immediate release	Randomized, active-controlled, double-blind, parallel assignment	Ortho-McNeil Janssen Scientific Affairs LLC; Grünenthal	74 sites; to determine eligibility, visit http://host.veritasmedicine.com/index.cfm?vip=6031-872-252200&sid=21080	NCT00986180
Study to determine the efficacy and safety of D-cycloserine in the treatment of neuropathic chronic low back pain	D-cycloserine vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Northwestern University; Rehabilitation Institute of Chicago	Thomas J. Schnitzer, M.D., Ph.D., 312-503-2315, tjs@northwestern.edu	NCT00125528
Study to evaluate the efficacy and safety of Bupivacaine TTS Patch in patients with chronic low back pain	Bupivacaine TTS Patch vs. placebo patch	Randomized, double-blind, placebo-controlled, parallel assignment	King Pharmaceuticals Research and Development; Durect Corporation	20 sites; Amber Hallenborg, 919-674-2893, amber.hallenborg@wwctrials.com	NCT01096966
Study to determine the efficacy and safety of EN3324 in subjects with moderate to severe chronic low back pain	EN3324 vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Endo Pharmaceuticals Inc.	55 sites; clinicaltrials@endo.com	NCT01043263
Study to evaluate the safety, efficacy, and tolerability of hydrocodone bitartrate controlled-release capsules in subjects with chronic low back pain	Hydrocodone bitartrate controlled-release capsules vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Zogenix Inc.	49 sites; Judith Myers, 510-550-8322, jmyers@zogenix.com	NCT01081912
Study to determine the effectiveness of spinal manipulation and the number of visits to a chiropractor for spinal manipulation, light massage, and ultrasound necessary for optimal relief of chronic low back pain	High-dose spinal manipulation plus ultrasound vs. moderate-dose manipulation plus low-dose massage plus ultrasound vs. low-dose spinal manipulation plus moderate-dose massage plus ultrasound vs. high-dose massage plus ultrasound	Randomized, open-label, active-controlled, parallel assignment	University of Western States; National Center for Complementary and Alternative Medicine	Jonathan Levine, 800-678-9072, jlevine@uws.edu	NCT00376350
Study to establish the safety and effectiveness of the TOPS System, used following decompression, in the treatment of lower back and leg pain, with or without spinal claudication, that results from moderate or severe lumbar spinal stenosis at one vertebral level between L3 and L5	TOPS System	Randomized, single-blind, active-controlled, single group assignment	Impliant Ltd.	16 sites; Dan Finan, 609-779-6800, ext. 404, dan.finan@impliantinc.com	NCT00405691
Study to establish the safety and efficacy of the Biostat System when used for treatment of chronic low back pain due to symptomatic internal disc disruptions	Biostat System vs. saline injection	Randomized, double-blind, placebo-controlled, parallel assignment	Spinal Restoration Inc.	14 sites; Jeff F. Doerzbacher, 512-225-0405, ext. 14, jeffdoerzbacher@spinalrestoration.com	NCT01011816
Study to determine the individual efficacy of transforaminal epidural corticosteroids and transforaminal epidural etanercept in patients with lumbosacral radiculopathy	Transforaminal epidural injections of etanercept vs. transforaminal epidural injections of methylprednisolone vs. transforaminal epidural injections of saline	Randomized, double-blind, placebo-controlled, parallel assignment	Johns Hopkins University; Walter Reed Army Medical Center; National Naval Medical Center; Womack Army Medical Center; Landstuhl Regional Medical Center; Massachusetts General Hospital	Two sites; Steven P. Cohen, M.D., scohen40@jhmi.edu	NCT00733096

*Based on a Sept. 3, 2010, search of www.ClinicalTrials.gov for studies that match the following parameters: open studies, interventional studies, "low back pain," United States, and phase II and III.