CLINICAL TRIALS UPDATE: HEADACHE*

Description	Interventions	Design	Sponsors/Funding	Location/Contact	NCT ID No.
Phase II study to determine the efficacy of an intravenous bolus of metoclopramide after 2 hours in the treatment of **acute migraine in children**	Intravenous metoclopramide vs. placebo	Randomized, double-blind, placebo-controlled, crossover assignment	Children's Hospital of Philadelphia	Dr. Nicholas S. Abend, 215-590-1719, abend@email.chop.edu	NCT00355394
Phase III study to evaluate the efficacy and safety of rizatriptan for the treatment of **acute migraine in children and adolescents**	Rizatriptan benzoate vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Merck	176 sites; 888-577-8839	NCT01001234
TEAM – A phase II and III study to evaluate the efficacy and safety of Treximet for the treatment of **acute migraine in adolescents**	Treximet (sumatriptan and naproxen sodium) vs. placebo	Randomized, double-blind, placebo-controlled, crossover assignment	Premiere Research Institute; GlaxoSmithKline	Four sites; Ashley L. Poulette, 561-296-3820, ashpriresearch@aol.com	NCT01016678
Phase III study to evaluate the efficacy of combined behavioral and pharmacological treatment on **chronic daily headache in children aged 10-17 years**	Coping skills training plus amitriptyline vs. headache education plus amitriptyline	Randomized, double-blind, active-controlled, parallel assignment	Cincinnati Children's Hospital Medical Center; National Institute of Neurological Disorders and Stroke	Cincinnati Children's Hospital Medical Center; Janelle Allen, 513-636-1840	NCT00389038
Phase III study to evaluate the efficacy, safety, and tolerability of telcagepant for the prevention of **menstrually related migraine in female patients with episodic migraine**	Telcagepant potassium vs.placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Merck	131 sites; 888-577-8839	NCT01125774
Phase II study to evaluate the efficacy of DR-105 for decreasing the frequency and severity of **menstrually related migraine headaches**	DR-105 vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Duramed Research	17 sites; Sally M. Fedon, Pharm.D., 215-293-7279, medicalaffairs@barrlabs.com	NCT00781456
Phase I and II study to assess the preliminary efficacy of a low omega-6 plus high omega-3 diet and a low omega-6 diet alone on headache frequency and severity in patients with **chronic daily headache**	Low omega-6 plus high omega-3 diet vs. low omega-6 diet	Randomized, double-blind, active-controlled, parallel assignment	University of North Carolina, Chapel Hill; Mayday Fund	Chanee E. Lynch, 919-966-8586, chanee_lynch@med.unc.edu	NCT01157208
Phase II study to test the effects of a novel emotional awareness and expression intervention against relaxation training or no intervention for **college students with chronic headaches**	Emotional awareness and expression training vs. relaxation training vs. no intervention	Randomized, open-label, parallel assignment	Wayne State University	Mark A. Lumley, Ph.D., 313-577-2773, mlumley@wayne.edu	NCT00956969
Phase III study to evaluate the efficacy of a novel ibuprofen formulation in the treatment of **episodic tension-type headache**	Novel ibuprofen formulation vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Wyeth	Pfizer ClinicalTrials.gov Call Center; 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com	NCT01077973
Study to evaluate the efficacy of octreotide compared with compazine for **emergency department treatment of migraine headache**	Octreotide vs. compazine	Randomized, double-blind, active-controlled, parallel assignment	C.R. Darnall Army Medical Center	Dr. Michael A. Miller, 254-288-8303, michael.miller3@amedd.army.mil	NCT00274170
Phase II study to evaluate the effect of percutaneous closure of a patent foramen ovale on the incidence of **migraine headaches**	AMPLATZER PFO Occluder vs. sham procedure	Randomized, double-blind, sham-controlled, parallel assignment	AGA Medical Corp.	31 sites; Michele Davies, mdavies@amplatzer.com	NCT00355056
Phase I and II study to determine the efficacy and safety of ethosuximide in the prevention of **episodic migraine among veterans**	Ethosuximide vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Department of Veterans Affairs; Thomas Jefferson University; University of Pittsburgh	VA Pittsburgh Health Care System; Dr. Kathy L. Gardner, 412-360-6185, kathy.gardner@va.gov	NCT01122381
Phase III study to determine the efficacy and safety of botulinum toxin A (Botox) in **migraine headaches**	Botulinum toxin A (Botox) open-label or blinded vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Yale University	Yale Neurology Clinic; Dr. Diana Richardson, 203-737-1831, diana.richardson@yale.edu	NCT00660192
CMTT – A phase III study to determine if adding propranolol to topiramate treatment will further reduce the headache burden for people with **chronic migraine**	Propranolol LA plus topiramate vs. topiramate plus placebo	Randomized, double-blind, placebo-controlled, parallel assignment	The EMMES Corporation; National Institute of Neurological Disorders and Stroke; Ortho-McNeil Janssen Scientific Affairs, LLC; CRC Operations Center	66 sites; Michelle Greenberg, 800-305-7811, nindscrc@ninds.nih.gov	NCT00772031
Phase II study to determine the efficacy and safety of ramelteon (Rozerem) for reducing the number of **migraine headaches** over a 12-week period	Ramelteon (Rozerem) vs. placebo	Randomized, double-blind, placebo-controlled, parallel assignment	Swedish Medical Center; Takeda Global Research & Development Center Inc.	Swedish Medical Center; Patricia M. Barrodale, 206-215-3502, pat.barrodale@swedish.org	NCT00739024
Phase III study to determine whether, in patients diagnosed with **vertical heterophoria**, the symptoms of dizziness, headache, and/or anxiety are reduced or eliminated when a kind of correction called vertical prism is added to the patient's normal eyeglass prescription	Glasses with lenses containing prismatic correction vs. glasses without prismatic correction	Randomized, double-blind, crossover assignment	Vision Specialists of Birmingham; Essilor International	Vision Specialists of Birmingham (Mich.); Dr. Mark S. Rosner, 248-258-9000, msr50@comcast.net	NCT00785135
IIHTT – A phase II and III study to determine the safety and efficacy of treatment strategies for restoring and protecting vision loss in patients with **idiopathic intracranial hypertension and mild vision loss**	Acetazolamide plus a formal weight loss counseling program vs. placebo plus a formal weight loss counseling program	Randomized, double-blind, placebo-controlled, parallel assignment	St. Luke's-Roosevelt Hospital Center; National Eye Institute; University of Rochester; University of Iowa; University of California, Davis	New York Eye and Ear Infirmary; Katy Tai, 212-979-4251, ktai@nyee.edu	NCT01003639

*Based on an Aug. 3, 2010, search of www.ClinicalTrials.gov for studies that matched the following parameters: open studies, interventional studies, "Headache," United States, and phase II and III.