Clinical Research Information

What is a Clinical Trial?

Clinical trials are health-related research studies in humans that follow a pre-defined protocol. There are several types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

Why participate in a clinical trial and what should be considered?

Clinical trial participants can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Clinical trial participants should learn as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about the purpose, the care expected while in a trial, and the cost of the trial.

What is the Idiopathic Intracranial Hypertension Treatment Trial (IIHTT)?

This study is funded by the National Eye Institute and is the first study of its kind to examine the effectiveness of medication (acetazolamide) and diet as compared to diet and placebo (sugar pill) in people with this condition. This study will also try to uncover the cause of IIH.

Why is diet an important part of IIHTT and how will diet be managed?

IIH is a condition that almost always occurs in overweight people. The IIHTT is being carried out to study the effect of both medication and weight loss on the treatment of increased intracranial pressure. Dietary counseling will be managed by the New York Obesity Research Center (NYORC). A weight loss coach will be assigned to each participant to help with the weight-loss program.

What is the Study Drug Acetazolamide (Diamox)?

The study medication is acetazolamide, an approved FDA medication that is used to treat conditions such as glaucoma, altitude sickness and some cardiac conditions. Acetazolamide is the most frequently used medication to treat IIH, but its effectiveness has never been proven.

NORDIC Network of Sites in USA & Canada

Bascom Palmer Eye Institute, Miami, FL
Bethesda Neurology, LLC, Bethesda, MD
Beaumont Eye Institute, Royal Oak, MI
Casey Eye Institute, Portland, OR
Dean A. McGee Eye Institute, Oklahoma City, OK
Department of Ophthalmology at UAB, Birmingham, AL
Department of Ophthalmology and Visual Sciences, Iowa City, IA
Doheny Eye Institute, Los Angeles, CA
Duke Eye Center, Durham, NC
Greater Baltimore Medical Center, Baltimore, MD
Hotel Dieu Hospital, Kingston, Ontario, Canada
Jules Stein Eye Institute, Los Angeles, CA
LSU Surgical Facility, Baton Rouge, LA
Mason Eye Institute, Columbia, MO
Medical University of South Carolina, Charleston, SC
Massachusetts Eye and Ear Infirmary, Boston, MA
Michigan State University, East Lansing, MI
Neuro-ophthalmic Consultants Northwest, Seattle, WA
Neuro-Ophthalmology & Balance Disorders Clinic, Tallahassee, FL
Neuro-ophthalmology Department of Neurology, Peoria, IL
New Jersey Medical School, Newark, NJ
New York Eye and Ear Infirmary, NYC, NY
OSU Eye Physicians and Surgeons, LCC, Columbus, OH
Raleigh Neurology Associates, Raleigh, NC
Saint Louis University Eye Institute, Saint Louis, MO
Stony Brook Ophthalmology, Stony Brook, NY
SUNY Upstate Medical University, Syracuse, NY
The Emory Clinic – Emory University, Atlanta, GA
The Eye Care Group, New Haven, CT
The Montréal General Hospital, Montreal, Quebec, Canada
The Mount Sinai Medical Center, New York, NY
University Eye Institute, Houston, TX
University of Colorado, Aurora, CO
University of Michigan, W.K. Kellogg Eye Center, Ann Arbor, MI
University of Minnesota, Minneapolis, MN
University of Pennsylvania, Dept. of Ophthalmology, Philadelphia, PA
University of Rochester Eye Institute, Rochester, NY
University of St. Louis, St Louis, MO
University of Texas Science Center, San Antonio, TX
University of Utah, John A. Moran Eye Center, Salt Lake City, UT
University of Virginia, Charlottesville, VA
Wake Forest University Eye Center, Winston-Salem, NC
Wilmer Ophthalmological Institute, Baltimore, MD

NORDIC Clinical Trials

Idiopathic Intracranial Hypertension Treatment Trial

A Multi-center, Double-blind, Randomized, Placebo-controlled Study

Michael Wall, MD, Study Director
James Corbett, MD, co-Director

For more information or if you are interested in becoming a study participant please call:
Ann Marie Lavorna, BSN RN
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631-444-4090 or 631-444-4485

NORDIC Clinical Trials

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What is Idiopathic Intracranial Hypertension (IIH)?

Idiopathic intracranial hypertension is a condition of high spinal fluid pressure of unknown cause which causes swelling of the optic nerve head. Swelling of the optic nerve head can result in damage to the fibers of the optic nerve and permanent vision loss. IIH occurs 9 times more frequently in women than men and 90 percent of patients are overweight or obese.

What are the symptoms of IIH?
The symptoms most commonly reported by IIH patients are:
- **Headache** -- present in nearly all patients with IIH and is usually severe, throbbing and daily.
- **Episodes of temporary lost or foggy vision** (visual obscurations) -- in one or both eyes that usually last less than 30 seconds and are followed by full recovery of vision.
- **Whoooshing Noises** (Pulsatile intracranial noises) -- occur in one or both ears.
- **Visual Loss** -- the most serious problem patients will experience. Approximately 5% of IIH patients go blind in at least one eye.
- **Double vision**

What is NORDIC?

The Neuro-Ophthalmology Research Disease Investigator Consortium (NORDIC) is an organized extensive group of Neuro-Ophthalmologists and other doctors, who have developed a structured organization to perform clinical research with the support of the National Eye Institute of the NIH, other funding agencies, and industry. Neuro-Ophthalmology is a subspecialty of Neurology and Ophthalmology that addresses scientific and medical aspects that connect both specialties.

NORDIC was created to provide the organization and operational capability to address unanswered questions about neuro-ophthalmologic disease including IIH and pursue new clinical trial research over a broad range of scientific and medical issues that affect vision, eye movements, pupil function and visual quality of life. NORDIC will perform multi-site observational and treatment trials that concern disease risk, diagnosis, treatment and other management-aspects of those disease entities or new therapies, which could not be studied without a clinical research organization.

How to find out more information about NORDIC or to participate in the IIHTT Study?

If interested in learning more about NORDIC, please contact the NORDIC Manager, NORDIC Headquarters: (212) 636-3516 www.NORDClinicalTrials.com

If interested in learning more about the IIHTT study, please contact:

Patrick Sibony, MD
Principal Investigator 631-444-4090

Ann Marie Lavorna, BSN RN
Study Coordinator 631-444-4485

Or contact:
The NORDIC Project Manager, Ann Stoutenburg at the Data Coordination and Biostatistics Center: 585-273-2529

The NORDIC Regional Project Coordinator, Bernadette Farrell at NORDIC Headquarters: 212-636-3406

Who is eligible for the IIHTT study?

Patients of either sex, 18 to 60 years of age who:
- Have met criteria for IIH
- Have mild visual loss
- Are willing to be assigned randomly to either placebo or acetazolamide
- Are willing to follow up as scheduled
- Are willing to participate in the weight-loss program

What are the study procedures if willing to participate in the IIHTT study?

A spinal tap is done at the time of diagnosis to be sure the spinal fluid pressure is elevated and there is no evidence of tumor or infection. The spinal tap is repeated at the end of the six month study to judge the effectiveness of treatment. At the beginning there will be an extensive neurological examination performed. Visual field and eye examinations will be done monthly, as will photographs of the back of both eyes after eyes are dilated. Blood studies will be carried out to measure vitamin A levels and a sample of blood, for research purposes only, will be drawn for genetic evaluation.

What are the benefits of the study?

There is no guaranteed benefit as a participant in the IIHTT study with the possible exception of the detailed care received for vision and for any overweight condition. Participants will be carefully followed for any evidence of progression of visual loss. Should loss of vision occur, treatments with other medications or with surgery will be given if needed. As a participant in the IIHTT study, all participants will be part of an important treatment trial for a condition that has no proven therapy.

What are the risks of the study?

There is a chance the condition will worsen, whether or not there is study participation. Vision and optic nerve swelling will be monitored carefully throughout the study. If vision worsens, study participation will be withdrawn and treatment by a treating physician will be provided.

Mild side effects from the study medication may also be experienced such as tingling of lips and limbs and feeling tired. Some food and carbonated beverages may taste metallic or different.

Before a decision is made whether or not to be in this study, a doctor will discuss the study and other options that are available.