Effect of Phenytoin on the Ganglion Cell Layer in Patients with Optic Neuritis

NCT02939937

April 15, 2019

[Informed Consent form]

This Informed Consent Form is for men and women who attend FARABI EYE HOSPITAL, and who we are inviting to participate in research on optic neuritis. The title of our research project is "Effect of phenytoin on the ganglion cell inner layer thickness and visual field in patients with acute optic neuritis." Optic neuritis is an inflammation that damages the optic nerve, a bundle of nerve fibers that transmits visual information from your eye to your brain. Pain and temporary vision loss in one eye are common symptoms of optic neuritis. The drugs that are currently used to help people with optic neuritis do not prohibit nerve fiber loss which is the main cause for loss of vision in optic neuritis. Also, the high-dose regimen used is associated with some recognized adverse effects. There is a drug which is suggested to better save the nerve fibers. The reason we are doing this research is to find out if this is actually true. This research will involve taking oral medicines thrice daily as well as two follow-up visits to the clinic. We are inviting all adults with unilateral acute optic neuritis who attend FARABI EYE HOSPITAL to participate in the research on this drug. Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for disease optic neuritis, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier. The drug we are testing in this research is called phenytoin. You should know the possible side effects associated with this drug: • fever, swollen glands, sore throat, trouble breathing, painful mouth sores, sores around your eyes; • skin rash, easy bruising or bleeding, severe weakness; • severe muscle pain; • nausea, vomiting, upper stomach pain, loss of appetite, dark urine, jaundice (yellowing of the skin or eyes); • bone pain (especially in your hips, legs, or lower back), trouble with walking; or • severe skin reaction--fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling. Common phenytoin side effects may include: • dizziness, drowsiness, confusion, nervousness; • nausea, vomiting, constipation; • tremors, slurred speech, loss of balance or coordination; • rash; • abnormal eye movement; • headache; or • sleep problems (insomnia). A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does. The research takes place over six months. In total, you will be asked to come 2 times to the clinic. At the end of six months, the research will be finished. We will follow you closely and keep track of any unwanted effects or any problems. We may refer you to some other medical specialists to manage the symptoms of the side effects or reactions. Or, we may stop the use of the drug. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step. By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better. The information that we collect from this research project

will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except doctor Gholizadeh, Dr. Aghsaiifard, Dr. Yadegari, and the University Ethics Board, in order to monitor preservation of my rights. You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected. If you do not wish to take part in the research, you will be provided with the established standard treatment available at the clinic. If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Dr. Alireza Gholizadeh, FARABI EYE HOSPITAL, Tehran, Iran I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. Print Name of Participant_____ Signature of Participant _____ Date _____ Day/month/year