PFIZER
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A RESEARCH STUDY LOOKING AT CHANGES IN EYESIGHT FROM USING PREGABALIN

"Prospective randomized 12-week controlled study of visual field change in subjects with partial seizures receiving pregabalin or placebo"

WHAT IS THIS STUDY ABOUT?

This **three month** study will look at people between **18-65 years old**, taking their **own** anti-seizure medications **in addition to either the study drug (pregabalin) or a placebo.** The aim is to **look for changes in eyesight.** Visual fields (the area you can see with each eye) and visual acuity (how clear your vision is) will be measured in people before, during, and after the study.

HOW WILL THE STUDY BENEFIT ME? WHAT IS THE POTENTIAL HARM?

The study is being done to learn more about how the study drug, pregabalin (Lyrica), can be used safely. This study may not provide a benefit to you personally. Pregabalin has been approved by the FDA in the United States for use as an add-on treatment for people with partial seizures, as well as for neuropathic (nerve) pain and fibromyalgia. However, as pregabalin came into use around 2004, another anti-seizure medication, vigabatrin, was reported to cause visual field disturbances or problems with eyesight, and so pregabalin is being studied for any effects on vision.

HOW CAN I PARTICIPATE?

The first step is to see if the study is right for you at a **screening visit with a healthcare provider.** A study team member will explain the details of the study with you. **If you qualify** and are willing, **you can** give your consent to **participate.** (You can always choose to withdraw from the study at any time.) Some or all of the following tests will be done:

- medical history
- medication review
- physical examination
- neurological examination
- vital signs and weight
- electrocardiogram (heart rhythm test)
- blood samples
- electroencephalography (EEG or brain wave test)
- Questionnaires Regarding Mood and Self-Harm
- Computerized Tomography (CT SCAN) or Magnetic Resonance Imaging (which are; computerized pictures of your brain - if necessary)

Your eyes will also be examined at this time, including dilating your pupils to see the back of the eye.

If you are eligible for this study, you will be randomly assigned by chance (like the flip of a coin) to receive either pregabalin or placebo during the study. You have a 50% (1 in 2) chance of receive pregabalin and a 50% (1 in 2) chance of receiving placebo. You will take the study drug or the placebo, whichever you are assigned, in addition to your usual anti-seizure medications.

During the course of the study, you will have **several check-ups** with your healthcare provider. Some or all of the following will be done at these visits: physical exam, external eye exam, blood and urine sample collection, review of medications, and discussion of seizure frequency.

If you are found to have any visual effects, you will also have visual testing done at the follow-up visit. Assessment of any visual effects requiring follow-up will be supported by Pfizer.

WHO IS ELIGIBLE TO JOIN THE STUDY?

- ✓ People between the ages of 18-65
- ✓ Diagnosis of epilepsy with **partial (focal) seizures**
- ✓ Currently being treated with **one to three anti-seizure medications**
- ✓ If you are eligible for the study: All study visits, testing and medication will be provided to you, at no cost to you or your insurance.
- ✓ Transportation support is available to help you get to and from your study visits.
- ✓ Compensation for your time and inconvenience is available.
- ✓ Subjects who complete the study or who are withdrawn by the sponsor prior to completion may be eligible to receive six months of their anti-epileptic medications as prescribed by your doctor, at no charge to you or your insurance company.

EPILEPSY FOUNDATION

https://clinicaltrials.gov/ct2/show/NCT00351611

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