What is a clinical trial?

A clinical trial is a scientific study in which participants are assigned to one or more investigational drugs to answer questions about the treatment to see if it works, works better than other treatments, and has side effects.

What is an investigational drug?

An investigational drug is a substance that is being tested in clinical trials. It has been approved by the FDA for testing in people but has not been approved for treatment.

Why should I take part in this study?

Clinical trials or studies are important for medical advances. Current treatments for diseases are only available because of research study volunteers.

Who can participate in this study?

You may qualify for this study if:

- You are 18-80 years of age
- You have been diagnosed with isolated cervical dystonia

Your doctor will go over other study requirements to confirm if you qualify.



Thank you for your interest in the ASPEN trial.

For more information, please visit studycd.com or contact:

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TIRED OF YOUR CERVICAL DYSTONIA?

A Patient Guide for the ASPEN Trial

Ask your doctor if you're eligible for the ASPEN trial.



Introduction

Thank you for considering participation in the ASPEN trial for cervical dystonia. If you have been diagnosed with this condition, you may be frustrated or overwhelmed by the symptoms of cervical dystonia such as uncontrollable muscle contractions and movements of the head, neck, and shoulders. These muscle contractions may also cause other symptoms such as tremors, neck or shoulder pain. You may also notice changes to your mood and emotions, or you may feel depressed, avoid people and activities you usually enjoy, or have trouble sleeping. A clinical trial may be one way you can help researchers who are studying this disease.

What is the purpose of this study?

An investigational drug is being studied for patients who have isolated cervical dystonia. The purpose of this study is to evaluate if the investigational drug works and to determine its safety.



How long will the trial last?

At its longest, the study would be 39 weeks, including 21 days for screening.

The study is divided into 3 time periods:

- 01 Screening period (up to 3 weeks)
- 02 Treatment period (1 day)
- 03 Follow-up period (up to 36 weeks)

What can I expect if I decide to participate?

If enrolled in the study, you will receive one treatment of either the investigational drug or the placebo.

In-clinic visits would include an initial screening visit, a treatment visit, and follow-up visits at Weeks 2, 4, 6, 12, and every 4 weeks thereafter up to 36 weeks. Up to 12 in-clinic visits will be required over the course of the study. Lab tests, a physical exam that includes an examination of your nervous system, and surveys will be conducted at the in-clinic visits. Not all activities will occur at every visit.

What are my costs to take part in this trial?

You will receive all study-related procedures and the investigational drug at no cost.

How large is this study?

This study will be conducted at about 80 study sites in the US, Canada, and Europe with about 300 participants.

What risks are involved if I decide to participate?

Clinical trials are an important part of the research of new medicines. You may be able to help others with cervical dystonia in the future by enrolling in a clinical trial to test an investigational drug. There are possible risks involved with any clinical study. Your study doctor will review the risks with you, and you will be closely monitored throughout the study.