

Peyronie's Study

DESCRIPTION AND PURPOSE OF THE STUDY

The study doctor and Auxilium Pharmaceuticals, Inc., the sponsoring drug company, are conducting a research study of an investigational use of a drug called AA4500 (collagenase clostridium histolyticum). An investigational use of a drug is one that has not been approved by the United States Food and Drug Administration (FDA) in the United States, but may be tested in research studies such as this one. AA4500 was approved by the FDA in February 2010 for another disease indication called Dupuytren's Contracture, which is caused by abnormal or extra collagen that is deposited in the palm of the hand. The purpose of this study is to test whether AA4500 is safe and can reduce or correct the curvature of the penis caused by the collagen plaque. Another purpose of the study is to collect information from questionnaires that you will fill out at a few visits that assess the effects of the study treatment on your Peyronie's Disease.

As a participant in this study, you will receive as study treatment either AA4500 or placebo (placebo looks like AA4500 but has no active drug) as injections into your penile plaque along with a procedure called "modeling". Modeling is performed by the study doctor and by you at home, and it consists of bending and stretching exercises performed at the area of the plaque to stretch and lengthen the plaque. Be aware that this consent form refers to AA4500 as "study drug." This consent form may also refer to AA4500 plus modeling and/or placebo plus modeling as "study treatment."

If you receive the placebo in this study, you may be eligible to receive AA4500 in a follow up study after the completion of this study.

This is a double-blind study. This means that neither you nor your study doctor will know whether you are taking study drug or placebo. If medically necessary, the study doctor can find out what you are taking.

Your reactions to the study treatment (study drug plus modeling or placebo plus modeling) will be monitored throughout the study. You must tell the study doctor about any medications you have taken during the 30 days before enrolling into the study or any medication you plan to begin taking during the study. Before you take any medication during the study, you should first discuss it with the study doctor or study staff. This includes prescription medications, over-the-counter medications such as cough and

cold remedies, pain relievers, antacids, sleep aids, and herbal substances (such as St. John's Wort, ginkgo biloba, or kava kava), and in particular, aspirin or other blood thinners. While in the study, you may not use any penile stretching devices like the "pump" or "rack". You will also be asked to provide a list of all treatments you have taken for Peyronie's Disease, and the dates that you took the treatments, including pump or stretching devices.

You cannot use certain other treatments for the plaque (Peyronie's disease) as a participant in this study. If you decide to be in this study, you might have to stop taking your regular treatment during the entire study. If you stop your regular treatment to be in the study, your condition might get worse.

While you are in the study, you must:

- Follow the study schedule and instructions you are given.
- Come to the study center for all visits with the study doctor.
- Tell the study doctor or study staff about any hospital visits, changes in your health, or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time

Call to get more information and to see if you qualify



609-895-0735