What are the advantages of taking part in ZEDS?
You will be seeing your study doctors and study coordinators regularly. They will carefully review your medical history and your care. Your participation will help us understand the treatment options for **Herpes Zoster Ophthalmicus**.

Will it cost me anything to participate?
The study medicine will be provided to you free of charge. You or your insurance company will not be billed for the cost of the study visits related to HZO or the study medicine. You and/or your health insurance will be billed for the cost of medical care you receive while you're in the study if the care is not related to you taking part in the study. This includes any eye care that is not related to the study.

Are there any new drugs or procedures being tested?
No. The study drug Valacyclovir has been approved for the treatment of shingles for over 20 years.

Will my personal information be kept confidential?
Yes, you have a right to your privacy, and your participation in this study will be kept private. Only the study team and other people involved in the study will see your study records.

ZEDS

Zoster Eye Disease Study

Where can I get more information about this study?

More information about this clinical trial is on the following public websites:

www.med.nyu.edu/research/zoster-eye-disease-study

www.clinicaltrials.gov/

Who to Contact

Principal Investigator:

Study Coordinator:

Address:

Phone:

Email:

ZEDS

Zoster Eye Disease Study

A clinical trial investigating whether long-term treatment with a pill, Valacyclovir, will help reduce eye disease and/or chronic pain in patients with shingles affecting the eye.

NYU School of Medicine
NYU LANGONE MEDICAL CENTER

NIH National Eye Institute

Version date: 03/06/17
IRB approval date:

What is Zoster Eye Disease?
Shingles, often called Herpes Zoster, is a painful skin rash which is caused by the chickenpox virus. After a person has chickenpox, the virus stays in the body and remains dormant (asleep) in the nerve cells. At some point, the immune system may weaken, allowing the virus to become active again and cause shingles. After the rash goes away, a patient may experience severe pain. When shingles affects the eye, it is called **Herpes Zoster Ophthalmicus (HZO)**.

How is HZO treated?
The drug named Valacyclovir is used to treat patients for one week when they first show signs of the herpes zoster rash.

What is a clinical trial?
A clinical trial is a research study with volunteers that is designed to improve care for patients with health problems. Trials usually compare different treatments, including medications.

Why participate in a clinical trial?
Participants in clinical trials can play a more active role in their own healthcare, receive new treatments before they are widely available, and help others by contributing to medical research.

What is the Zoster Eye Disease Study (ZEDS)?
ZEDS is a multi-center randomized clinical trial to look at whether long-term treatment will be effective in decreasing eye disease and/or severe pain in patients with **Herpes Zoster Ophthalmicus**.

Patients who volunteer to participate in ZEDS will be randomly assigned (like flipping a coin) to take Valacyclovir or a placebo (an inactive pill) every day for one year.

There will be about 1050 patients who will be participating at approximately 60 eye doctors offices across the country.

ZEDS

Zoster Eye Disease Study

Can I participate in ZEDS?
You may be able to volunteer to join this study if you:

- had a rash from shingles over your eye
- have had certain types of eye disease from shingles affecting your cornea within the past year
- are 18 years old or older

Talk to your eye doctor or contact the ZEDS Study Team to learn more.

What happens if I volunteer for ZEDS?
If you want to take part in this study you will be asked to give your permission by signing a consent form. The study will be explained to you, and you will have the chance to ask questions before you sign. After giving your written permission you will be asked questions about your health and the study doctor will go over your eye medical records with you. You will be given a prescription to get a blood test to see how well your kidneys function. Women may be told that they need a pregnancy test.

An appointment will be made for another visit. At that visit, the study doctor will review your eye medical records again. You will have an eye exam, and the amount of eye pain you feel will be evaluated. You will be assigned to either the study drug or placebo, and you will be given enough pills to last three months and instructions on how to take them.

You will come back for study visits every three months for the next year and a half. At each visit the study doctor will go over your medical records and examine your eye. Your will receive more pills up until the one year visit. Even after you stop taking the pills after one year, you will still come in for visits for the doctors to go over your medical history and to examine your eye.

Who is organizing and funding the trial?
The study was designed by expert eye doctors and scientists from leading hospitals and universities. ZEDS is funded through a grant from the National Eye Institute of the National Institutes of Health with additional support from NYU Langone Medical Center.