



## **RETINITIS PIGMENTOSA (RP)**

is a rare retinal degenerative disease. Early symptoms include loss of peripheral vision and difficulty seeing at night, but over time, the disease can lead to substantial blindness.

OCLI is conducting a clinical trial to assess the safety and effectiveness of a new investigational product, called BS01, for people with advanced RP.

OCLI is one of the leading ophthalmology practices in the United States: <https://www.oci.net>. Its primary site is located in Long Island, NY, with a satellite facility for vision testing in Manhattan.

BS01 was developed by Bionic Sight: <http://www.bionicsightllc.com/>

# What happens when a person develops RP, and how might BS01 help?

## *Normal vision*

In normal vision, light enters the retina through the photoreceptors. These cells convert the light into electrical signals and then pass them through the retina's circuitry to the optic nerve. The optic nerve then sends the signals on to the brain.

The brain uses these signals to create visual perceptions, such as perceptions of faces, objects, or the environment around you.

## *Retinal degenerative disease*

When a person develops a retinal degenerative disease, such as RP, the photoreceptors stop working. As a result, no signals reach the optic nerve. Without signals from the optic nerve, the brain is unable to get visual information, creating the condition of blindness.

## *BS01's mode of action*

Bionic Sight's approach is to bypass the problem - that is, bypass the photoreceptors and go directly to the optic nerve. If the optic nerve can be reactivated, then it can go back to sending signals to the brain. BS01 is an investigational gene therapy designed to reactivate the optic nerve.

## Who can participate in the study?

You may qualify if you:

- Have been diagnosed with RP
- Have advanced-stage blindness
  - this includes subjects who can barely see light up to those who can count fingers
- Are 18 years of age or older

## Does it cost to participate?

There is no charge for the study drug or for any of the study-related clinic visits or tests. But you and your health plan will have to pay for your regular medical care.

## If I participate, can I be sure I'll receive the study drug?

Yes. All subjects will receive BS01. You will be assigned to one of several groups, corresponding to different BS01 strengths.

## What are the steps involved in joining a trial?

1. *Provide written consent*
2. *Get screened for eligibility*
3. *Participate in the trial*

You'll be provided with an informed consent form, which you'll need to read and make sure you understand. A study coordinator will meet with you, so you can ask as many questions as you need before signing. It's important that you fully understand what will happen during the trial.

The study doctor and team will run tests to determine if you're eligible to participate (e.g., vision tests to assess your RP). You'll also be asked about your medical history, medications you're using, and other issues that may affect your ability to qualify for the trial.

If you are eligible, and if you choose to enroll, you'll be scheduled to begin the trial. You'll receive the study drug as a single injection to your eye under local anesthesia. After that, you'll return for follow up visits over the next year to check your eye, monitor safety, and assess the effectiveness of BS01. You'll also need to return for annual check ups and vision tests in years 2-5.

Remember that participation in a trial involves both receiving the study drug and attending all the follow up visits.

**If you are interested in participating in the BS01 trial, please contact the OCLI Research Department at (516) 593 4026.**

**To learn more about Bionic Sight and its approach to RP, please visit <http://www.bionicsightllc.com>**

## About Clinical Trials

Clinical research studies are an essential part of developing new treatments for people living with diseases or health conditions. They're important because they provide information about the safety and effectiveness of new drugs before they are approved for general use.

These studies are closely regulated. The investigators are required to follow standards set forth by the FDA and other regulatory agencies to protect patients. Each study must have an approved written protocol to ensure that all study procedures are conducted in accordance with regulations.