Clinical Study in NAION

To find out if you may be eligible for the study, please fill out a quick survey.

Find a Clinical Site

We are evaluating the safety and efficacy of an investigational drug to stop further vision loss in patients with early diagnosis of Nonarteritic Anterior Ischemic Optic Neuropathy (NAION). NAION is the most common cause of sudden optic nerve related vision loss in older individuals.

Criteria for Study Participation

- Aged 50 to 80 years old
- Experienced sudden vision loss in the last 14 days
- No treatment for current set of vision loss symptoms
- Other criteria to be evaluated at the clinical site

If you are experiencing vision loss, contact a medical professional as soon as possible.

Breaking mists, the Pap of Glen Coe
Artist: Keith Salmon

[Video to be displayed at bottom of page - https://app.frame.io/v/z9LXj1Jr]

About the Study:

What is the purpose of the study?

We are evaluating the safety and efficacy of an investigational drug to stop further vision loss in patients with early diagnosis of NAION.

What can patients expect?

- Meet with the doctor to discuss the symptoms
- Assessment of vision loss
- Evaluation for study participation

What are the criteria for study participation?

- Ages 50 to 80 years old
- Experience sudden vision loss in the last 14 days
- No treatment for current set of vision loss symptoms
- Other criteria to be evaluated at the clinical site

What will happen during the study?

- 8 visits will be completed over approximately 1 year
- Study treatments will be administered at 3 of the visits
- Eye exams will be conducted at each visit
- General health status will be monitored at every visit
- Visits generally take approximately 2-4 hours to complete
- Study-related costs are covered
- Reasonable travel costs may be reimbursed

Where is the study taking place?

The study will be conducted at multiple sites in several countries. Please click on "Find a Clinical Site", and fill out a quick survey to locate a participating clinical site. A full listing of the current participating clinics may be found www.clinicaltrials.gov, study number: NCT02341560.

Study Basics

What is the purpose of a study?

A clinical study investigates potential new treatments to confirm whether the medicine or treatment is safe and effective for a particular disease or condition.

How are clinical studies approved?

All clinical study applications are reviewed by the U.S. Food and Drug Administration to decide if the clinical study is appropriate and if it conforms to laws and international regulations that are in place to guide clinical studies and ensure they adequately protect human participants. In addition, Institutional Review Boards (ethics committees) review studies to ensure they are conducted in accordance with all federal, institutional, and ethical guidelines.

Who is the Principal Investigator?

The Principal Investigator is a doctor at a clinic site. The doctor, with his/her team of nurses, pharmacists and other health care professionals, is responsible for overseeing the health of the study participants at all stages of the study and ensuring the clinical study is conducted correctly.

What is Informed Consent?

If the clinical site believes you might qualify for the study, you will receive an Informed Consent Form to review. The Informed Consent Form will include information on, but not limited to:

- Eligibility criteria
- The possibility of receiving the investigational medicine or placebo
- Possible risks and benefits of the investigational medicine
- The risks of any side-effects
- Descriptions of any medical tests or procedures done in the clinical study
- Your rights and responsibilities as a research participant
- Your right to withdraw from a clinical study at any time, without consequence to ongoing medical care.
- Information on how your confidential health information will be handled.

Only after careful consideration should you provide written consent to participate in a clinical study.

What are the risks from participation in a clinical study?

The investigational drug used in this and other human clinical trials has been tested in animals. All of the information known about the study drug has been used to design this study and your health will be monitored

closely, but unforeseen problems could arise.

In addition:

- The study participant may experience potential side effects from the study medicine.
- The study medicine may not work for the clinical study participant.
- In a placebo-controlled study like this one, the study participant may receive the placebo and not the investigational treatment.

More information will be provided in an Informed Consent Form at the first study visit.

What happens if side effects occur from taking a medicine in a clinical study?

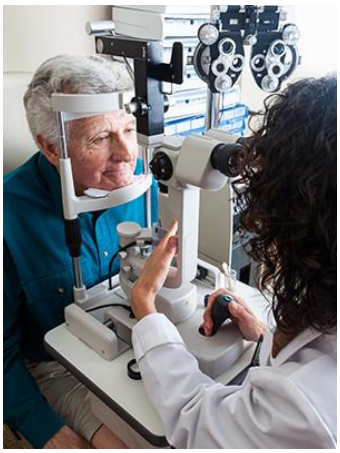
The study participant is asked at each visit to report any change in health status. If a side effect occurs, appropriate care will be provided.

Why should I participate?

There are many reasons why you may want to participate in a study – helping others by assisting with providing important information on new treatments, getting to try new treatments, and being more proactive with options for treatment of your condition. Study participation is voluntary. You can withdraw from this clinical study at any point in time without consequences to your medical care.

How can I participate in a clinical study?

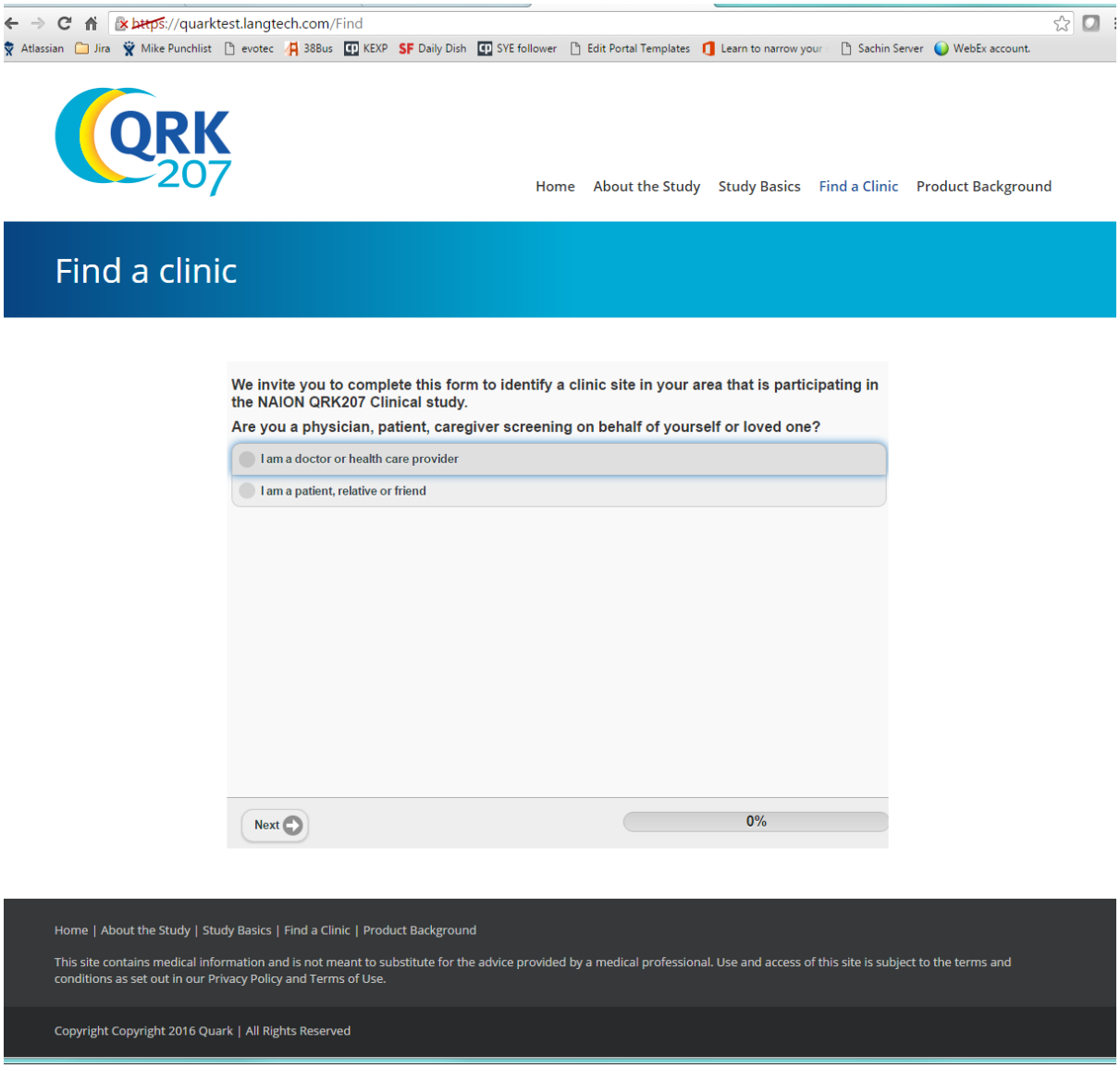
Please click on "Find a Clinical Site", and fill out a quick survey to locate a participating clinical site. Potential participants can also contact a clinic study site to see if they potentially qualify for the study by accessing study NCT02341560 onwww.clinicaltrials.gov.



Find a clinic

Please select your location below:

- United States – You will now be directed to a quick online survey to locate a participating clinical site.
- Outside of United States – You will now be directed to the clinicaltrials.gov webpage for this study, where you will find a list of participating clinical sites outside of the United States.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Learn to narrow your
Sachin Server
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Find a clinic
We invite you to complete this form to identify a clinic site in your area that is participating in the NAION QRK207 Clinical study.
Are you a physician, patient, caregiver screening on behalf of yourself or loved one?
I am a doctor or health care provider
I am a patient, relative or friend
Next
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Product Background

NAION:

QPI-1007 is a drug called a “small interfering ribonucleic acid”, or “siRNA”. siRNA drugs are designed to temporarily block cells from making specific proteins. QPI-1007 is designed to temporarily block the cells of the body from making a protein called “caspase 2”. High levels of caspase 2 have been found when cells are damaged due to lack of oxygen. Caspase 2 is thought to contribute to the death of these damaged cells. In NAION, nerve cells become damaged because of lack of oxygen. Temporarily stopping the nerve cells in the eye from making caspase 2 after they are damaged could give the cells more time to make repairs which may prevent further loss of vision and possibly improve vision. The study drug, QPI-1007, is injected into the eye because it needs to come into contact with eye nerve cells. QPI-1007 is being studied to determine its ability to treat vision loss that can occur in NAION.

To learn more about this product, visit the Quark website.