ABOUT RESEARCH STUDIES

Pharmaceutical companies use research studies like this one to learn more about investigational drugs before they are made available to the public. The results of this study will provide more information about the investigational drug being evaluated in this study. By taking part in this study, you will be making an important contribution to retinal ocular vein (RVO) treatment research.

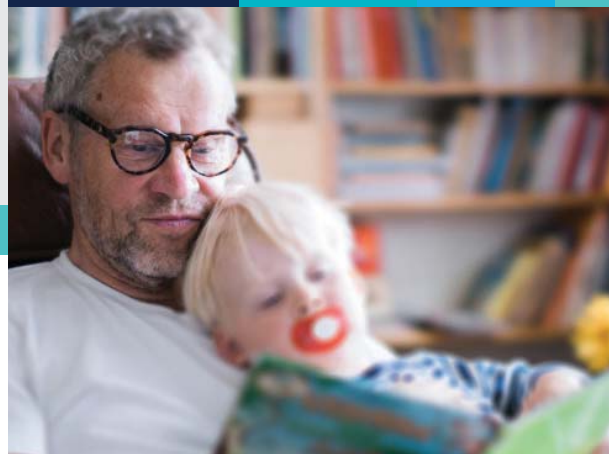
TO LEARN MORE ABOUT THIS STUDY, PLEASE CONTACT:

SAPPHIRE

13Apr2017_V2_CLS1003-301_Patient Brochure_English

WHAT ARE YOU MISSING DUE TO RVO?

Has sudden vision loss from Retinal Vein Occlusion (RVO) taken you from the things you love? Consider this research study of an investigational drug that may help restore vision.



BECAUSE OF YOUR SUDDEN VISION LOSS, YOU HAVE BEEN DIAGNOSED WITH RETINAL VEIN OCCLUSION (RVO).

This serious eye condition occurs when a blockage develops in one of the veins that returns blood from your retina. While your vision could return to normal on its own, unfortunately there is also a chance that your vision will not be as strong or clear as it was, due to long-term damage from RVO. Receiving medical treatment for RVO may help your recovery.

Available treatment options focus on either reducing inflammation that could be blocking the retinal vein, or stopping excess fluid from building up in the eye, both of which are related to RVO. You may have tried one or both of these options, but are still looking for an alternative option.

One option to consider is this study that is evaluating the combined use of an investigational drug for reducing inflammation and an approved drug that helps prevent excess fluid in the eye. By using these drugs together to treat two different aspects of the condition, doctors believe it might be a more effective way to treat RVO, which could offer a better outcome in restoring damaged vision.

If you are eligible for this study, you will receive injections of the approved drug and either the investigational drug or placebo, which looks like the investigational drug, but contains no active medication. The injections will be administered by the study staff about every 4 weeks for 24 weeks, and you may receive injections of the approved drug, as needed, for another 12 weeks. The results of this study will provide more information about the investigational drug and whether it could one day be used to help treat RVO.

WHO IS ELIGIBLE TO PARTICIPATE IN THIS STUDY?

To pre-qualify for this study, you must:

- Be at least 18 years of age
- Have been diagnosed with RVO in your eye within ≤ 9 months of beginning the study
- Have not received treatment for RVO

All study-related visits, tests, and medications will be provided at no cost. In addition, reimbursement for study-related time and travel may be provided.

WHAT WILL HAPPEN DURING THIS STUDY?

If you are eligible for this study, and you agree to participate, you will be randomly assigned (like the flip of a coin) to receive injections of the investigational drug or placebo, in addition to the approved drug. You have a 50% chance of receiving the investigational drug or placebo.

You will visit the study clinic about every 4 weeks to receive at least one injection. During your study clinic visits, doctors and the study staff will evaluate your health and progress through various tests and assessments. Your total study participation will last approximately 50 weeks and includes 12 study clinic visits.

WHAT ARE THE RISKS AND BENEFITS RELATED TO THIS STUDY?

As with any research study, there is no guarantee you will receive any benefit from your participation. It is also possible you could experience a side effect while in this study. The study staff will review the full list of side effects with you before you join the study.

Your health and safety will be monitored while you are in this study. The sponsor of this study was required to design a protocol, which explains all study procedures in detail. An independent review board responsible for participant safety reviewed this protocol and requires that it be followed exactly.

VISITS 9, 10, 11 (WEEKS 30, 36, 42)

You will receive IVT aflibercept injections at these visits, if needed.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Urine pregnancy test*
- Eye tests and exams

*Females of childbearing potential only

After the pre-dose tests and assessments are completed, you will receive an aflibercept injection, if needed.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 12 (WEEK 48)

This is the final clinic visit of the study.

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Blood and urine sample collections
- Eye tests and exams
- Questionnaires about your vision and quality of life
- Photographs of the eye

SAPPHIRE

RESEARCH STUDY PROCEDURES AND ASSESSMENTS

VISIT 1 (SCREENING)

These assessments and procedures will help study doctors and study staff members determine if you can participate in this study.

- Read and sign informed consent form
- Review of medical and ocular history
- Review of eligibility
- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Blood and urine sample collections
- Eye tests and exams
- Photographs of the eye

VISIT 2 (DAY 0)

You will receive injections of your study drug at this visit.

PRE-DOSE

- Review of eligibility
- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Urine pregnancy test*
- Eye tests and exams
- Questionnaires about your vision and quality of life

*Females of childbearing potential only

After the pre-dose tests and assessments are completed, you will receive two injections of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 3 (WEEK 4)

You will receive an injection of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Eye tests and exams

After the pre-dose tests and assessments are completed, you will receive one injection of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 4 (WEEK 8)

You will receive an injection of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Eye tests and exams

After the pre-dose tests and assessments are completed, you will receive one injection of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 5 (WEEK 12)

You will receive injections of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Urine pregnancy test*
- Eye tests and exams

*Females of childbearing potential only

After the pre-dose tests and assessments are completed, you will receive two injections of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 6 (WEEK 16)

You will receive an injection of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Eye tests and exams

After the pre-dose tests and assessments are completed, you will receive one injection of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 7 (WEEK 20)

You will receive an injection of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Eye tests and exams

After the pre-dose tests and assessments are completed, you will receive one injection of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

VISIT 8 (WEEK 24)

You will receive injections of your study drug at this visit.

PRE-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Heart rate and blood pressure measurements
- Urine pregnancy test*
- Blood sample collection
- Eye tests and exams
- Questionnaires about your vision and quality of life
- Photographs of the eye

*Females of childbearing potential only

After the pre-dose tests and assessments are completed, you will receive two injections of your study drug.

POST-DOSE

- Assessment of any side effects
- Review of medications you are currently taking
- Eye tests and exams

<<Principal Investigator Name>>
<<Address 1>>
<<Address 2>>
<<City, State Post Code>>
<<Telephone>>

SAPPHIRE

<<Patient Name>>
<<Address 1>>
<<Address 2>>
<<City, State Post Code>>

Research Study for People With Retinal Vein Occlusion (RVO)

Dear <<Patient Name>>

I would like to let you know about a research study that we are conducting. This study is evaluating an investigational drug as a possible treatment option for RVO.

Why is this study being conducted?
Doctors want to evaluate the combination of the investigational drug, which focuses on reducing inflammation, and an approved drug that helps prevent excess fluid in the eye. They believe that by combining these drugs to treat two different aspects of the condition, it might be a more effective way to treat RVO, which could result in a better outcome in restoring damaged vision.

Study doctors want to compare the investigational drug to placebo, which looks like the investigational drug, but contains no active medication. The results of this study will provide more information about the investigational drug and its effect, in combination with the approved drug, on RVO.

What will happen in this study?
If you are eligible, you will be randomly assigned (like the flip of a coin) to receive the investigational drug or placebo. You have a 50% chance of receiving injections of either study drug (investigational or placebo) in combination with the approved drug.

You will visit the study clinic about every 4 weeks for 24 weeks to receive at least one injection. You may also receive injections of the approved drug, as needed, for another 12 weeks. Your total participation in this study will last approximately 50 weeks and includes at least 12 study clinic visits.

Who is eligible to participate in this study?
To pre-qualify for this study, you must:

- Be at least 18 years of age
- Have been diagnosed with RVO in your eye within ≤ 9 months of beginning the study
- Have not received treatment for RVO

All study-related visits, tests, and medications will be provided at no cost. In addition, reimbursement for study-related time and travel may be provided.

To learn more about this study, or to find out if you may qualify, please contact <<contact name>> at <<contact number>>. Thank you for your consideration of this study, and we hope to hear from you soon.

Sincerely,

<<PI Name>>
Principal Investigator