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1. Study Name

What does this Summary Cover?

This is a summary of a clinical study that was done in people with diabetic macular oedema (DME). The summary has information about how the study was done and what the most important results of the study are. Researchers need to look at the results of many studies to know which medicines work best and are safest for patients.

Short Study Title

A study to evaluate the safety of THR-149 in subjects with DME.

Official Study Title

A Phase 1, open-label, multicenter, dose escalation study to evaluate the safety of a single intravitreal injection of THR-149 for the treatment of DME.

Protocol Number

THR-149-001

US Study Number

NCT03511898

Date of this Summary

Version 2.0 20-Mar-2020

2. Who Sponsored the Study?

Who Was the Sponsor of the Study?

The sponsor of the study was ThromboGenics. ThromboGenics planned for the study and paid for the study to be done.

Of note: ThromboGenics has changed name and is now called Oxurion.

How to Contact Oxurion?

You can contact Oxurion at +32 16 75 13 10.

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3. General Information About the Study

Where and When Was the Study Done?

The study was done in 7 study centers in the United States. The study started in May 2018 and ended in May 2019.

Why Was the Study Done?

The study was done to test a new medicine to treat DME. DME is an eye problem that can happen in people who have diabetes. People with diabetes have too much blood sugar, which can damage the blood vessels in the back of their eye. As a result, these blood vessels can break easily and leak, causing the light sensitive tissue in the back of the eye (which is called the retina) to swell. This can lead to vision problems because the retina, and especially its central part (which is called the macula), is very important for vision. If left untreated, DME may lead to blindness.

There are already a few treatment options available for DME. These work for many people with DME, but not for all. That is why new medicines are needed.

The new medicine that was tested in this study is called THR-149. This was the first study in which THR-149 was tested in people. That is why the main goal of the study was to make sure that THR-149 is safe. The other goals of the study were to check whether THR-149 could help to improve vision and reduce the swelling in the back of the eye in people with DME.

4. Who Took Part in the Study?

Twelve (12) people with DME took part in the study. They were 6 men and 6 women. Their average age was 69 years. The youngest person in the study was 51 years old and the oldest person was 81 years old.

5. Which Medicine Was Tested?

The medicine that was tested is called THR-149. THR-149 blocks a protein called plasma kallikrein. Plasma kallikrein can activate another protein (called bradykinin), which can make blood vessels in the back of the eye leak. By blocking plasma kallikrein, bradykinin will be blocked as well. This could stop the blood vessels from leaking. THR-149 could hence work as a treatment for DME.

All people in the study received one injection with THR-149 into one of their eyes. Three (3) different concentrations of THR-149 were tested. The first 3 people who joined the study got the lowest concentration of THR-149, the next 3 people got the middle concentration and the last 6 people got the highest concentration. The people who took part in the study did not know which concentration they got, but the study doctors and the researchers did.

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6. How Was the Study Done?

For each person who took part in the study, there were 6 check-ups after the visit during which they got the injection with THR-149. The visits were done over the course of 3 months.

Everyone in the study was asked to tell the study doctor about any medical problems they had while they were in the study. This was needed to make sure that the researchers learned about any side effects that the injection with THR-149 may cause.

On top of that, during each visit, the study doctor did a complete eye check-up, including a vision test. For the vision test, the people were asked to read letters from a chart. The better the vision, the more letters a person can read. In addition, a machine was used to measure the swelling of the back of the eye.

7. What Were the Side Effects?

What Are Side Effects?

Side effects are unwanted medical problems that happen when a medicine is given. Side effects can be serious (for instance when it is life threatening, or when the person who gets the side effect needs to stay in the hospital because of it, or if it causes lasting damage), or non-serious (all other side effects). In a clinical study, all medical problems that start after the medicine is given are considered side effects. For each side effect, the study doctor evaluates whether it may be caused by the medicine. For each side effect, he / she also evaluates whether it is serious.

Were There Any Side Effects That Could Be Caused by the Injection with THR-149?

None of the people in the study had serious side effects which the study doctor thought were caused by the injection with THR-149.

One (1) person in the study had a side effect which the study doctor thought was caused by the injection with THR-149. This side effect was mild and had disappeared spontaneously after a few days. The researchers believe that it was caused by the injection itself, rather than by THR-149.

8. What Were the Overall Results of the Study?

Safety of THR-149

The study found that one injection of THR-149 is safe.

Improvement of Vision

After one injection with THR-149, on average, the people in the study could read more letters on the vision chart than before the injection. The improvement in vision started on the day after the injection and vision was still improved at the last check-up, at 3 months after the injection.

Reduction of the Swelling in the Back of the Eye

On average, the swelling in the back of the eye did not reduce after one injection with THR-149.

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9. How Has This Study Helped Patients and Researchers?

The study found that one injection of THR-149 is safe. The results of the study also suggest that THR-149 may work to improve the vision of people with DME. However, this was only the first study in which THR-149 was tested. More studies will need to be done to better understand if THR-149 is a safe medicine that works as a treatment for DME.

10. Are There Plans for Further Studies?

The next study, called the KALAHARI study, is being planned. Its protocol number is THR-149-002 and its EU study number is 2019-001506-17. Its US study number was not yet known at the time this summary was prepared.

Information on this study will appear in the EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/ctr-search/search) and on ClinicalTrials.gov (https://clinicaltrials.gov/ct2/home)

11. Where Can I Find More Information About This Study?

To learn more about study THR-149-001, you can find more detailed information on this website:

https://clinicaltrials.gov/ct2/home	Search for US study number: NCT03511898, or for protocol number: THR-149-001