IS THE RAINIER STUDY AN OPTION FOR YOU?

Questions and answers

for people considering the RAINIER study

RAINIER

Introduction

Based on your diagnosis of idiopathic pulmonary fibrosis (IPF), you may be eligible to join the RAINIER study, which is assessing a potential new treatment for this condition.

The information in this brochure answers some of the questions that you, or your friends and family, may have about the study, as you consider whether or not to take part. If you have any other questions, please ask the person named at the end of the brochure.

What is a clinical research study?

A clinical research study is a scientific study that examines the safety and effectiveness of potential new treatments. The studies are designed by medical professionals to answer specific questions such as how the drug works in different people, which doses are most effective and safe, and if the drug improves a person's health.

All approved medical treatments must go through this process, meaning that clinical studies are necessary for creating new treatments for many different illnesses.

What is the RAINIER research study for?

At this time, there is no known cure for IPF, and the main treatment options are oxygen therapy and lung transplantation. In some countries, there is also a medicine which can be prescribed. Because of the limited treatment options, scientists and doctors are very interested to investigate new medicines for IPF.

This clinical research study is looking at whether an investigational drug is safe and if it can help to slow the progression of IPF. It will involve approximately 500 people with IPF from all around the world.

What is the Investigational Drug?

The investigational drug blocks the action of a key enzyme which is thought to be involved in the development of scar tissue (fibrosis) in the lungs.

It is referred to as an 'investigational drug' because we need to investigate whether it is safe and can slow the progression of fibrosis when taken as a medicine by people with IPF.

Who can take part in this study?

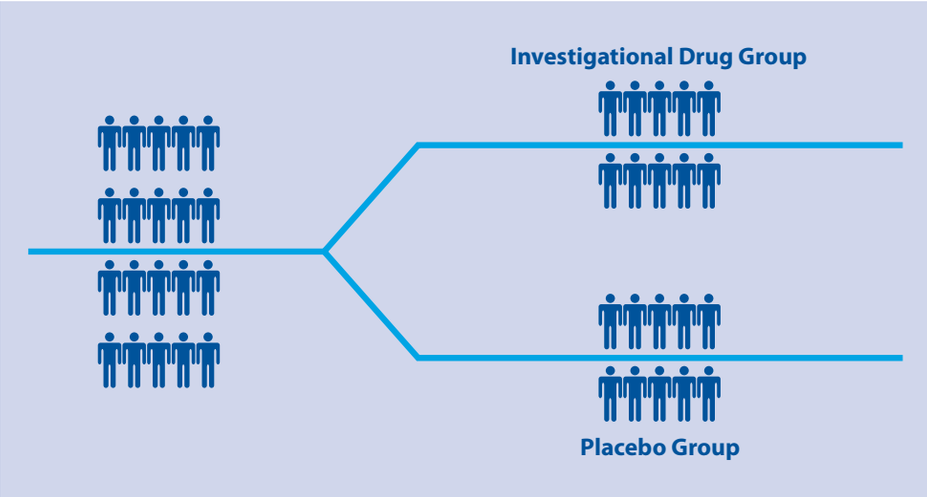
You may be able to take part in this study if you:

- Are between the ages of 45 and 85
- Have been diagnosed with IPF
- Are not actively listed on a lung transplant list.

What drug would I need to take?

You would need to take study drug for up to 3.5 years. The study drug you take would be either the investigational drug or placebo. Placebo is a substance that looks like the investigational drug but contains no active ingredient.

Half the people who join the study will receive the investigational drug and half will receive placebo. You would be allocated by chance to receive either the investigational drug or placebo - this is called "randomization".



The study drug is a **once weekly injection** with a needle in your skin (a shot). With the training and support that you will receive from the study doctors and study staff, you should be able to give yourself these shots at home (perhaps with help from your caregiver). Although this may seem difficult at first, many people with conditions like diabetes and arthritis do this routinely. The study drug must be stored in your refrigerator.

Can I ask to receive the investigational drug if I join the study?

No. We need information from participants who are not taking the investigational drug as well as from participants who are.

Will I know if I am taking placebo?

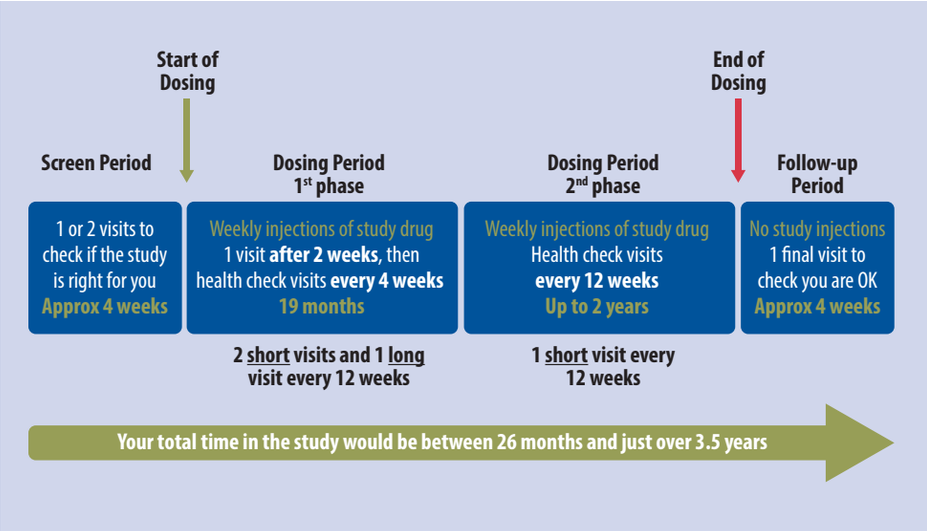
During the study neither the study doctors nor the participants will know whether they are receiving the investigational drug or the placebo. This is called "blinding".

You will be monitored, and if your disease gets significantly worse, you may be given other suitable treatments in addition to the study drug. In case of a medical emergency, there are standard study procedures that allow doctors to find out quickly which study drug you are taking.

How much time will the study take?

Taking part in this study will last just over 3.5 years at the most. The time you will remain on the study depends on when you join the study, and whether or not your IPF gets worse. During this time, you will need to visit the study clinic at most 32 times. For the first 19 months you would come to study visits every 4 weeks. After that it would only be every 12 weeks (approximately 3 months).

The schematic shows the different stages of the study.



Will it cost me anything to be in the study?

The study drug used in this study will be given to you at no charge. All study clinic, professional, diagnostic, and laboratory fees for tests and procedures that are part of this study will be provided at no cost to you. The study staff will also talk to you about support for travel and other expenses.

What side effects might occur?

All medications have potential side effects; some can be mild while others are more serious. However, not everyone will experience side effects. The study staff will review the potential side-effects of the investigational drug and study procedures with you.

The study is designed to minimize the risk and impact of side-effects by:

- Not allowing people who are at a higher risk of more severe side-effects to join the study
- Monitoring for early signs of problems.

Participants are encouraged to contact the study team at ANY TIME with concerns about possible side-effects.

What are the possible benefits of taking part in this study?

Different people have different reasons to take part in clinical research - it is entirely voluntary.

- It is important that you understand that there is no guarantee that you will receive personal benefit from taking part in this study. You might receive placebo. If you receive the investigational drug, it may or may not slow the progression of your IPF.
- The RAINIER study is hoping to find a new way to treat IPF. Your contribution to the study may benefit the community, scientists, and doctors who work with IPF by providing increased knowledge and information about IPF and the effectiveness of the investigational drug. The study will help determine if the investigational drug can be used as a treatment for IPF in the future.

What do I need to do if I take part in the study?

Study participants need to:

- Attend study visits for up to approximately 3.5 years
- Inject the study drug every week
- Use effective birth control (if appropriate)
- Tell the study doctors about any side-effects and/or new medicines
- Not take other medicines for IPF whilst you are in the study (unless your IPF gets significantly worse and your doctor thinks it is necessary)
- Not take part in any other research studies while participating in the RAINIER study.

On the back of the brochure you will find a chart showing what would happen at each type of visit. At most visits you will have:

- A physical exam and vital sign check (e.g. pulse and blood pressure)
- Breathing tests (e.g. spirometry and DLco)
- Blood tests
- A study staff member watch you give your injection
- A study staff member check for any potential side effects.

At the longer visits, in addition to the above, you would have

- A walking test
- A questionnaire.

What happens next?

If you want to take part in the RAINIER study, the study doctors and nurses will first need to explain the study to you in more detail. Contact information for the study team is provided below.

CardioPulmonary Research Center
at St. Luke's Hospital

(314)439-LUNG (5864)

THANK YOU FOR CONSIDERING THE RAINIER STUDY

Study Visit Schedule

Assessment	Screen visit	Start of dosing	Short visit	Long visit	End of study
Scan*	✔		✔ †		
Questionnaire	✔	✔		✔	✔
Physical examination	✔	✔	✔	✔	✔
Vital signs (e.g. pulse, blood pressure)	✔	✔	✔	✔	✔
ECG (heart measurements)	✔				
6-minute walk test	✔	✔		✔	✔
Breathing tests (spirometry & DLco)	✔	✔	✔	✔	✔
Whole body breathing test (plethysmography)	✔				
Pregnancy test‡	✔	✔	✔	✔	✔
Blood draws	✔	✔	✔	✔	✔
Training/checking self injection	✔	✔	✔	✔	
Check for potential side-effects	✔	✔	✔	✔	✔

*May not be needed if you had one in the last 3 months
†For US participants only - Extra HRCT Scan at week 54
‡Women only – if of child bearing potential