

Symptoms of cirrhosis may include:

- Fatigue
- Abdominal pain and/or nausea
- Weakness
- Edema: fluid buildup (swelling) in the legs, ankles or feet
- Weight loss
- Jaundice: a yellow color to the skin and eyes
- Loss of appetite
- Easily bruising
- Itching

Complications from cirrhosis may include:

- *Ascites*: fluid buildup in the abdomen that causes swelling of the abdomen, abdominal discomfort and increased weight
- *Spontaneous bacterial peritonitis*: an infection in the abdominal cavity that may occur with ascites
- *Esophageal variceal bleeding*: when abnormal, enlarged veins in the lower part of the esophagus leak blood or rupture
- *Hepatic encephalopathy*: impaired brain dysfunction that occurs when the liver can no longer remove toxic substances from the blood
- *Hepatorenal syndrome*: decreased kidney function or kidney failure that can occur when nitrogen-containing waste products build in the bloodstream

There is no known cure for cirrhosis, so many of the treatment options focus on preventing further complications and the progression of the liver scarring. In order to find new and better treatments for individuals living with cirrhosis, doctors and researchers need to conduct medical research.

A medical research study is designed to answer important questions about the safety and effectiveness of new, investigational medications by testing them on actual patients. Before medications can be approved for public use, they must be tested in research studies.

If you have cirrhosis of the liver, you may qualify to participate in our research study.

Please read-on to learn more and to see how you can be a part of this research study.

What should I do now?

If you are interested in taking part in this research study, please discuss it with your family and then talk to your doctor if you received this from someone other than your doctor. You can also talk to the person who gave you this brochure, or refer to the contact information below.

The persons depicted are models used only for illustrative purposes.

Are you,
or is
someone
you know
living
with
cirrhosis,
of the
liver?

If so, you may want to learn about participating in our research study of an investigational medication for adults with cirrhosis.

Cirrhosis is a phase of chronic liver disease when scarring develops on the liver and causes poor liver function. Some of the causes of cirrhosis include alcoholism, hepatitis B, hepatitis C and fatty liver disease.

For more information, call

Colon and Digestive Health Specialists
480-815-6100
arizonadigestivecenter.com
Renee Hoffman

What is the purpose of this research study?

In this research study, we will evaluate the safety and effectiveness of an investigational medication designed to prevent complications from cirrhosis.

We will enroll approximately 420 individuals with cirrhosis in this study, which will be conducted at around 100 different research centers in the United States.

How do I know if I can be in this research study?

Qualified participants must:

- Be 18 years of age or older
- Have been diagnosed with cirrhosis of the liver
- Be suffering from the buildup of fluid in the abdomen (called ascites)
- Have not yet experienced any other major complication of liver cirrhosis
- Be willing to participate up to 28 weeks
- Have a family member or friend who is willing to help during the study

What will my involvement consist of if I decide to participate?

If you qualify and are enrolled in the research study, you can expect your participation to involve up to ten visits to the research center over a period of 28 weeks, which is seven months. You will also have five phone calls from the study staff in between visits.

There are three parts to this study: a *screening period*, a *treatment period* and a *follow-up visit*.

Screening period: The study staff and the study doctor will review the study with you during your first visit. Then, you will be asked questions about your current medical condition and your medical history. You will also be given tests and examinations to see if you meet the requirements to participate in the treatment period of the study. If the study doctor decides that you are eligible to participate in the treatment period of the study, you will be told when to return for your next visit.

Treatment period: Before receiving treatment, you will be asked more questions about your current medical condition and given additional tests and examinations to make sure you continue to qualify for the study. After that, you will be assigned to one of six groups. Five of the groups will be assigned to take the investigational medication and the sixth

group will be assigned to take a placebo. The placebo looks similar to the investigational medication, but contains no active ingredients. Group assignments will be made at random, similar to drawing straws, and you will have an equal chance of being assigned to any of the six groups. Since group assignments will not be disclosed to you or to the study doctor, neither of you will know whether you are assigned to take the placebo or the investigational medication. You will take your assigned study medication once daily at bedtime for 24 weeks.

Follow-up visit: After your last treatment period visit, you will have a final visit where you will be given tests and examinations and then asked questions about your overall health.

Are there risks to me if I am in this research study?

There may be potential risks to you while participating in this research study and these will be discussed with you in detail before you participate. All medications and medical procedures carry a risk of side effects; therefore, it is possible that you may experience some discomfort or other side effects associated with the use of the study medication. You should report any side effects to the study doctor.



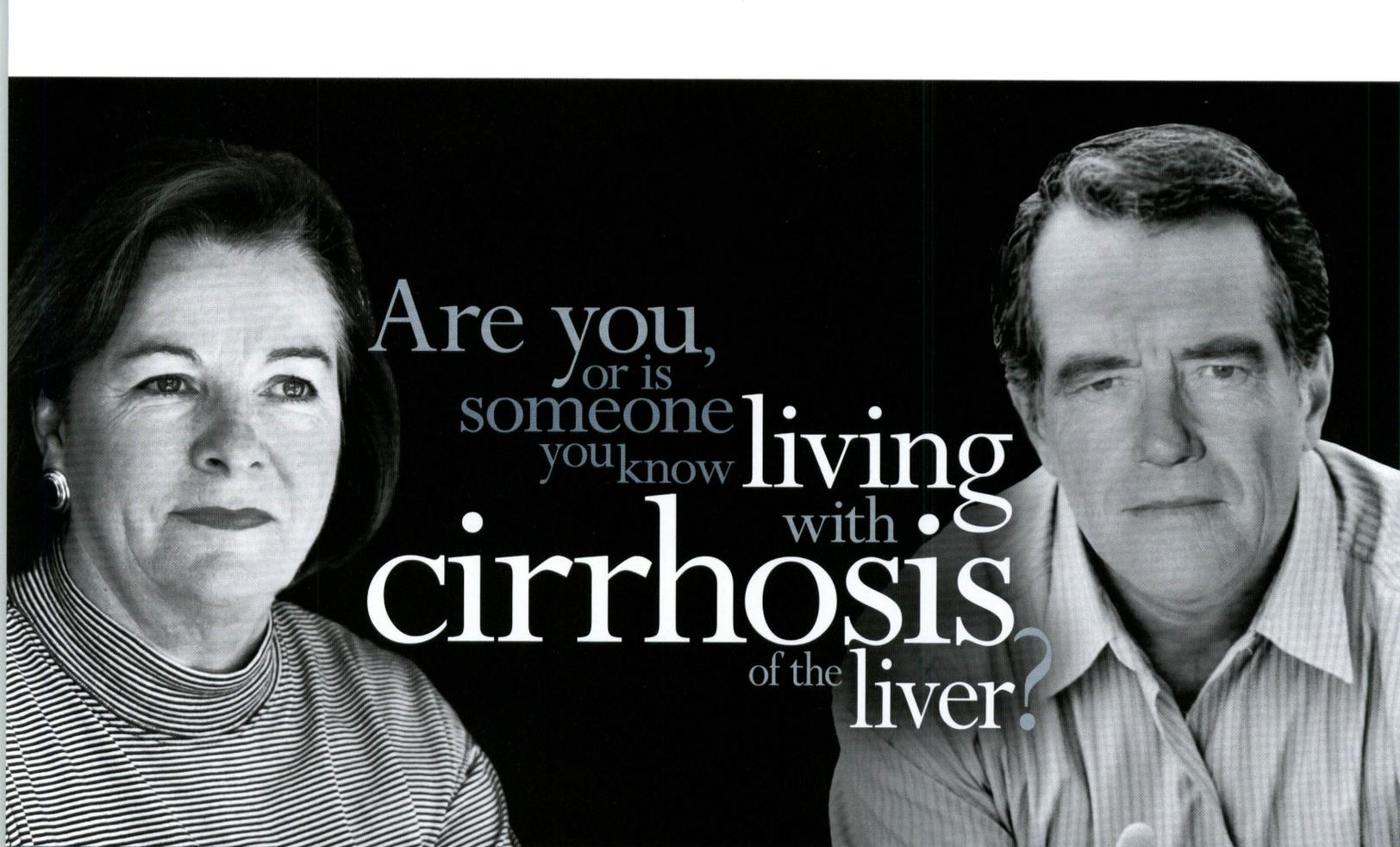
The complete list of requirements will be discussed with you by the study doctor.

Does it cost anything to participate?

All medical examinations, evaluations and study medications are provided to qualified participants at no cost. Financial compensation may also be provided to those who qualify to cover time and travel expenses related to the research study. The amount of available compensation will be discussed with you by staff at the research center.

What are the potential benefits of participating?

You may or may not receive any benefit from the study medication you are assigned to use during this research study. However, your participation may help to answer questions regarding the safety and effectiveness of the study medication. This could provide new information about the treatment for liver cirrhosis, which may help other patients in the future.



Are you,
or is
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you know living
with
cirrhosis
of the liver?

If so, please contact us about our research study to evaluate the safety and effectiveness of an investigational medication designed to prevent major complications from cirrhosis.

Qualified participants must:

- Be 18 years of age or older
- Have been diagnosed with cirrhosis of the liver
- Be suffering from the buildup of fluid in the abdomen (called ascites)
- Have not yet experienced any other major complication of liver cirrhosis
- Be willing to participate up to 28 weeks
- Have a family member or friend who is willing to help during the study

Qualified participants receive:

- Study-related care and study medication at no cost
- Compensation for time and travel

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