

Model Volunteer Consent Form, #5

*Other collaborators in the
Mertz /*

Ribavirin Treatment of Hantavirus Illness Acquired in the United States

Purpose

We offer ribavirin as a treatment for the "Mystery Illness."

"Mystery Illness" is an infection caused by a type of hantavirus. The illness is now called "Hantavirus Illness." This hantavirus is a tiny germ, a virus. It comes from a mouse. Some people infected with hantavirus get sick but get well. Since May, more than half of people sick with hantavirus illness have died.

There are different types of hantaviruses. We are not sure of a way to treat the type here. But ribavirin may be a treatment. A study suggested that ribavirin may help cure illness caused by a related hantavirus.

The use of ribavirin to treat hantavirus illness is experimental.

There is no medicine now to treat this type of hantavirus illness. Ribavirin is a medicine used in the U.S. When given by breathing it in, it helps cure a severe viral lung infection in children. But we do not know if ribavirin can treat the hantavirus illness. We feel ribavirin may be able to treat your illness. Because ribavirin is experimental for hantavirus it can be used only in a research study.

The purpose of the research is to see if ribavirin can treat the hantavirus illness.

We also will check the side-effects and safety of ribavirin.

Procedure

Dr. [Investigator], [Institution], is in charge of the research in [State].

Doctors in [Hospital] can use ribavirin under the research plan by Dr. [Investigator].

For the treatment, we will give ribavirin injections by vein for 10 days.

We will give it every 6 hours for 4 days, then every 8 hours for 6 more days. The first dose will start right away. We will give bigger doses in the 4 days, and smaller doses the last 6 days. Those are the same doses used for many years to treat other viruses.

We will get lab tests every day.

Before we give the first dose, we will get some urine to test for hantavirus and check your kidneys. We will get 3 tubes of blood to check your blood, liver, and kidneys. If you are a woman, we will ask you if you are pregnant; we will do a urine or blood test for pregnancy.

While you get ribavirin we will get 3 tubes of blood each day to check your blood count, liver, and kidneys. We will get 1 tube of blood a month from now, to confirm the infection by hantavirus. We will save some blood and urine samples to do research; we want to learn how to better diagnose and treat the hantavirus illness.

Risks:

Only people with hantavirus illness should get ribavirin.

We think you are infected with hantavirus. But if we find out by our tests that you do not have hantavirus illness we will stop the medicine. If the ribavirin causes damage to you, we will stop the medicine.

We cannot give ribavirin to women who are pregnant.

When tested in pregnant animals, ribavirin caused severe birth defects or death of the unborn animals. Thus, if given to a pregnant woman, ribavirin may cause severe birth defects or her unborn baby may die. So, we will not give ribavirin to pregnant women. That is why we test women for pregnancy, and ask about the history of last menstrual period.

Women who receive ribavirin must not become pregnant for 3 months.

The medicine can stay in the body for 3 months. Because it can harm an unborn baby, women should not get pregnant for 3 months after finishing it. If you are a woman, you must not get pregnant for 3 months.

Ribavirin may cause minor changes in the blood.

Most people who treated with ribavirin elsewhere got a mild anemia, or low blood count. The low blood count did not cause permanent damage. After the 10 day treatment, the blood count returned to normal.

Also, about 1 of every 50 patients who received ribavirin had slightly higher bilirubin in the blood; bilirubin can cause some people's skin to look a little yellow. The bilirubin returned to normal after finishing the medicine. Less than 1 of every 250 patients had a small increase in uric acid for a while; it returned to normal.

Ribavirin may have other risks we do not know about.

It may have a rare side-effect or reaction not known now. Any medicine can, very rarely, cause death from an allergic reaction.

Benefits

Ribavirin might help you.

There is now no other medicine for hantavirus illness. We hope ribavirin will treat this hantavirus because a study suggested that it may help cure illness by a related virus.

If you decide not to take ribavirin, we will give you the best standard treatment we can.

We will give all patients the best care we can, whether they take ribavirin or not.

Confidentiality

We will guard your privacy.

We will keep information about you and your taking part in this study confidential to the best of our ability. We will not use your name outside this study. If you take part, the U.S. Centers for Disease Control and Prevention, and the U.S. Food and Drug Administration, may check your medical records. A court could order us to show medical records to other people, but that is not likely.

All reports to the [government], community, other doctors, and medical journals will not have any patient name.

Questions

If you have questions about the study, call Dr. [Investigator] (at) ____-____

Call Dr. [Investigator] in [City] at ____-____ between [times]. All other hours, call () ____-____ and ask for [On-call]

If you have an injury or reaction that may be caused by ribavirin or procedures, please call Dr. [Investigator] at ____-____ right away. The [Hospital] will give you [any emergency / all] care you need.

Cost and Compensation

The ribavirin is given to you free.

There is no charge for the medicine.

[Care] will be provided you for [unexpected / any] adverse affects ribavirin

There is [no / a] program to pay patients for adverse affects.

Rights as a research volunteer

Taking part in this study is voluntary.

If you do not take part, you will have no penalty and lose no [care or services]. You may stop taking part at any time, with no penalty or loss of any [care or services] to which you are otherwise entitled.

You may stop taking ribavirin at any time. We may stop it if we feel stopping is best for your health. We will tell you any information we find that may affect your willingness to keep getting the medicine.

We may contact you later about taking part in a follow-up study related to ribavirin or the hantavirus illness. You may choose to take part or not at that time.

For answers to your questions about a complaint, grievance, other concerns, or legal claims, call [IRB, Risk office] at (____) ____-____

[State of New Mexico has laws that may help people who think they have been treated carelessly. Claims under those laws must be made soon.] Call or write:
[Office and person].

I agree to take part in the research study
_____ *Illness.*

Signature: _____
[or thumb-print]

itness: _____

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