Clinical Study Results

CSL Behring

Research Sponsor: CSL Behring

Medicine Studied: CSL112

Study Purpose: A study to learn how safe CSL112 was in patients with heart disease who also have kidney disease

Thank you!

Thank you for taking part in the clinical study for the study medicine CSL112. You and all of the participants helped study doctors learn more about using CSL112 to help people with heart disease who also have kidney disease.

CSL Behring sponsored this study and thinks it is important to share the results of the study with you and the public. We hope it helps you understand and feel proud of your important role in medical research.

If you have questions about the results, please speak with the doctor or staff at your study site.

What is happening with the study now?

You were in the study for up to about 10 weeks, but the entire study took about 10 months to finish. The study started in August 2016 and ended in June 2017.

The study included 83 participants in Germany, Hungary, Israel, the Netherlands, and the United States.

CSL Behring reviewed the data collected when the study ended and created a report of the results. This is a summary of the main results of that report.

Why was the research needed?

In this study, the doctors wanted to find out if CSL112 was safe to take for participants with both heart and kidney disease. They also wanted to find out if the participants had any medical problems that might be related to CSL112.

Patients with heart disease can develop serious medical problems related to their heart and arteries. One of these problems is cholesterol building up in their arteries. This can lead to heart attacks. CSL112 is a study medicine that is made with a protein that may help prevent heart attacks by removing these build-ups.

Creatinine is a substance that is naturally produced by the body. If a person's kidneys are not working well, the amount of creatinine in his or her blood may increase. So, the study doctors measured any large creatinine increases in the blood of the participants throughout the study.

The main questions study doctors wanted to answer in this study were:

- Did the participants who got CSL112 have serious adverse events related to their kidneys?
- Did the participants who got CSL112 have a large increase in creatinine in their blood?
- What medical problems did the participants have?

What kind of study was this?

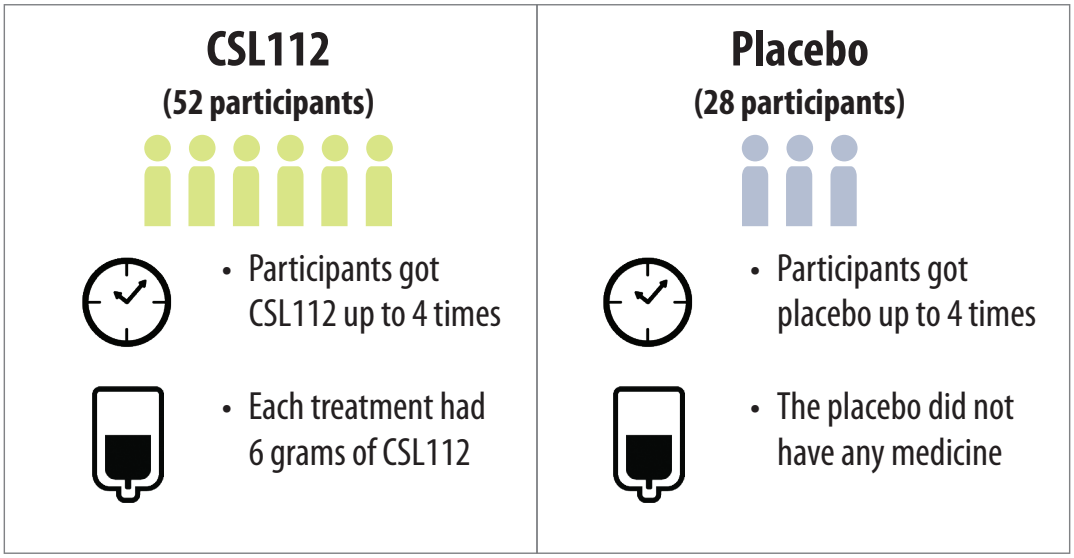
To answer the questions in this study, the study doctors asked for the help of men and women with both heart and kidney disease. The participants in this study were 36 to 89 years old.

This study compared CSL112 to a placebo. A placebo is given in the same way as the study medicine, but it does not have any medicine in it. The placebo used for this study did not contain the protein that is in CSL112. This study used a placebo to help make sure any of the effects seen in the participants who take the study medicine are actually caused by the study medicine. Both CSL112 and the placebo were given through a needle into a vein also known as an IV.

The participants in this study could get either CSL112 or a placebo. A computer program was used to randomly choose the treatment each participant got. Study doctors do this so that comparing the results of each treatment is as accurate as possible.

This was a "double-blind" study. This means none of the participants, doctors, or other study staff knew what treatment each participant got. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, CSL Behring was provided information about which treatment the participants got so they could create a report of the study results.

The chart below shows the treatments in this study:



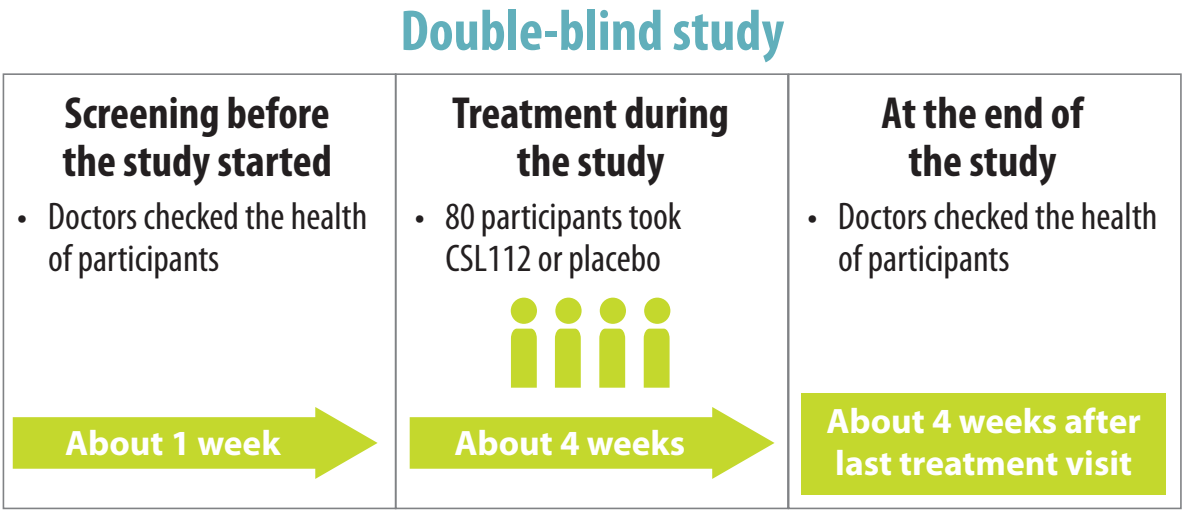
What happened during the study?

Before the study started, the doctors did a physical exam to make sure the participants could join the study. They also took blood and urine samples and checked the heart and kidney health of the participants.

During the study, 83 participants were randomly selected to get either CSL112 or a placebo, but 3 left the study before getting any treatment. The 80 participants who stayed in the study visited their study site 6 times during this treatment period. At some visits they got their assigned treatment, of either CSL112 or a placebo. At other visits, the doctors only checked the health of the participants.

At the end of the study, the participants visited their study site 1 more time. The doctors did a physical exam to check their health again.

The chart below shows how the study was done:



What were the results of the study?

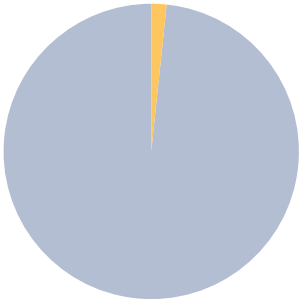
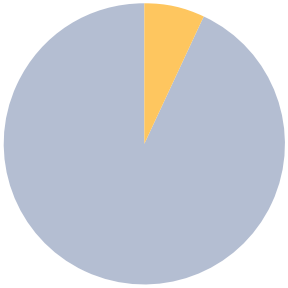
This is an overall summary of the main results from this study. The results each participant had might be different from the overall summary results. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

Did the participants who got CSL112 have serious adverse events related to their kidneys?

Overall, the participants who got CSL112 did not have more serious adverse events related to their kidneys compared to the participants who got the placebo. An adverse event is any medical problem that happens during a study. Adverse events may or may not be related to treatment.

To answer this question, the doctors studied the serious adverse events the participants had that they thought might be related to the kidneys. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

In this study, the doctors found that:

CSL112	Placebo
 1.9% of participants had serious adverse events related to their kidneys. This was 1 out of 52 participants.	 14.3% of participants had serious adverse events related to their kidneys. This was 4 out of 28 participants.

These adverse events were:

- kidney damage
- kidney failure
- poisoning of the kidneys
- sudden kidney failure

The study doctors did not think these adverse events were related to the study treatments.

Did the participants who got CSL112 have a large increase in creatinine in their blood?

Overall, fewer participants who got CSL112 had large increases in creatinine in their blood compared to participants who got the placebo.

In this study, the doctors found that:

CSL112	• 4.0% of participants had large increases in creatinine in their blood during the study. This was 2 out of 50 participants.
Placebo	• 14.3% of participants had large increases in creatinine in their blood during the study. This was 4 out of 28 participants.

What medical problems did the participants have?

Medical problems that study doctors thought might be caused by the treatment are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, is medically significant, requires hospital care, or results in death.

During the study, doctors thought these adverse reactions might be caused by CSL112, but more research is needed to know whether a treatment actually causes an adverse reaction. The websites listed at the end of this summary have more information about the adverse reactions that happened in this study.

The results below are for the 80 of the 83 participants who got study treatment.

How many participants had serious adverse reactions?

There were 1.3% of participants who had serious adverse reactions during the study that the doctors thought might be related to treatment. This was 1 out of 80 participants.

There were 0.0% of participants who got CSL112 who had serious adverse reactions during the study that the doctors thought might be related to treatment. This was 0 out of 52 participants.

There were 3.6% of participants who got the placebo who had serious adverse reactions during the study. This was 1 out of 28 participants. This serious adverse reaction was kidney failure.

None of the participants in this study died because of serious adverse reactions.

How many participants had adverse reactions?

There were 6.3% of participants who had adverse reactions during the study that the doctors thought might be related to treatment. This was 5 out of 80 participants. More participants who got CSL112 had adverse reactions compared to the participants who got the placebo.

What adverse reactions did the participants have?

Adverse reactions are medical problems that the study doctors thought might be related to treatment. The adverse reactions that happened during the study are listed below.

Adverse reactions during this study

	CSL112 (Out of 52 participants)	Placebo (Out of 28 participants)
Blood bilirubin increased (a sign of liver damage)	1.9% (1)	0.0% (0)
Breathing too quickly	1.9% (1)	0.0% (0)
Increased levels of alanine aminotransferase in the blood (a sign of liver damage)	1.9% (1)	0.0% (0)
Skin swelling at the IV needle site	1.9% (1)	0.0% (0)
Kidney failure	0.0% (0)	3.6% (1)

How has this study helped patients and researchers?

In this study, the doctors learned more about how CSL112 works and how safe it is in patients with heart disease who also have kidney disease.

- Overall, the participants who got CSL112 did not have more serious adverse events related to their kidneys than the participants who got the placebo.
- Overall, fewer participants who got CSL112 had large increases in creatinine in their blood compared to participants who got the placebo.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this 1 study. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

Further clinical studies with CSL112 are planned.

Where can I learn more about this study?

You can find more information about this study by searching on the websites listed below. If a full report of the study results is available, it can also be found there.

- www.clinicaltrials.gov Once you are on the website, type **"NCT02742103"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home & Search"**. Then, type **"2015-003017-26"** in the search box and click **"Search"**.

The full title of your study is: A Phase 2, Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group, Study to Investigate the Safety and Tolerability of Multiple Dose Administration of CSL112 in Subjects with Moderate Renal Impairment and Acute Myocardial Infarction

The protocol number of your study is: CSL112_2001

CSL Behring sponsored this study and has its headquarters at 1020 First Avenue, King of Prussia, PA 19406 USA.

The phone number for the CSL Behring Information Center is 610-878-4000.

The email address for CSL Behring Clinical Trial information is clinicaltrials@cslbehring.com.

Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

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THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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