

Read about this clinical trial's results



Hello!

Thank you for being in this clinical trial!

You helped doctors learn about a trial medicine called **inclisiran**. The trial medicine is for teenagers with **heterozygous familial hypercholesterolemia (HeFH)**. We hope you feel proud of your role!



What is a clinical trial and why did this trial happen?

A **clinical trial** is research to learn about a medicine. In this trial, doctors wanted to answer these questions about **inclisiran** in teenagers with **HeFH**:

- Did **inclisiran** lower teenagers' "bad" cholesterol from before treatment to 1 year of treatment?
- What medical problems happened to teenagers during this trial?

What is heterozygous familial hypercholesterolemia (HeFH)?

Heterozygous familial hypercholesterolemia (HeFH) is passed from parent to child. It causes high cholesterol. **Cholesterol** is a type of fat in the blood. When cholesterol is high, it can build up in blood vessels and block blood flow. This can cause serious health problems, like heart attacks.



There are 2 main types of cholesterol:

- **LDL cholesterol**, or “bad” cholesterol, which can build up in the blood vessels and cause a heart attack
- **HDL cholesterol**, or “good” cholesterol, which helps the body break down other types of cholesterol and protects against heart attacks



What is inclisiran?



Inclisiran is a trial medicine created to lower LDL cholesterol in the blood. You say **inclisiran** as “in-kli-sir-an.”



A **trial medicine** means that doctors are studying it to learn if it works.



Teenagers got **inclisiran** as injections under their skin on their belly.

Who was in this trial?



141

141 teenagers with **HeFH** were in this trial. All teenagers had **HeFH** and high LDL cholesterol, even though they were taking medicines to lower cholesterol.



12

to 17

years old



17



boys



66

girls

75

Where did this trial take place?

The map below shows how many teenagers took part in each country.



What happened during this trial?



This trial had 2 parts. In **Part 1**, teenagers got one of these:

- 300 milligrams (mg) of the trial medicine called **inclisiran**
- A **placebo**



What's a placebo?

A placebo has no medicine in it, but looks like the trial medicine. You say placebo as “pluh-see-boh.”
Using a **placebo** helps doctors better understand how **inclisiran** works.



Doctors used a **computer** to assign teenagers by chance to get one of these:



93 teenagers
got inclisiran



48 teenagers
got a placebo

In **Part 1**, the teenagers, their families and the doctors did not know if they were getting **inclisiran** or **placebo**.
Teenagers got **inclisiran** or **placebo** 3 times over 1 year.



What happened during this trial?



Teenagers who completed **Part 1** were in **Part 2**.
In **Part 2**, 139 teenagers got **inclisiran**.



They got **inclisiran** as injections up to 3 times over 1 year.



Doctors checked their health for up to 1 month after their last trial visit.

What was learned from this trial?

Did inclisiran lower teenagers' "bad" cholesterol from before treatment to 1 year of treatment?

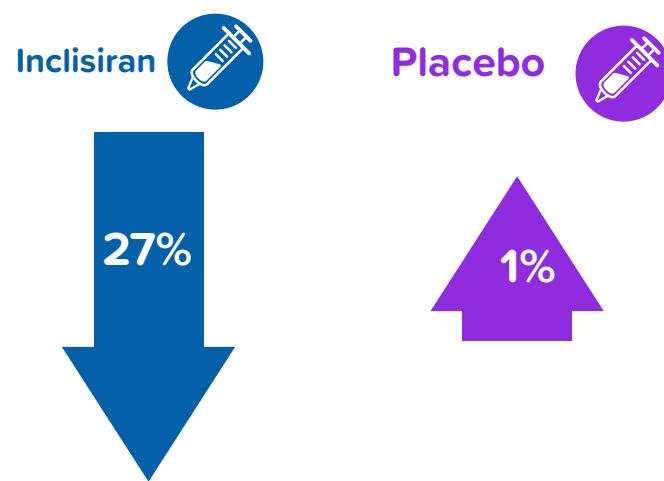


During **Part 1**, doctors measured the level of "bad" or LDL cholesterol in teenagers' blood before and after 1 year of treatment. They compared the change in "bad" cholesterol in teenagers who got **inclisiran** to those who got **placebo**.



Answer

Overall, "bad" or LDL cholesterol was lower at 1 year of treatment in teenagers who got **inclisiran** compared to those who got **placebo**.



Teenagers who took **inclisiran** had their cholesterol go down 27% after 1 year of treatment

Teenagers who took **placebo** had their cholesterol go up 1% after 1 year of treatment

What was learned from this trial?

What medical problems happened to teenagers during this trial?



Doctors checked teenagers and wrote down all medical problems they had during the trial, even if they were not caused by **inclisiran**.



Answer

In **Part 1**, 103 teenagers had medical problems during the trial. 4 teenagers had serious medical problems.

In **Part 2**, 87 teenagers had medical problems during the trial. 6 teenagers had serious medical problems.

The most common serious medical problem was:



Serious allergic reaction to food

Other common medical problems were:

- COVID-19
- Common cold
- Flu
- Headache
- Problems where injections were given, such as redness or pain

Thank you!

Trials like this cannot happen without you and others who join.



Doctors need the results from many trials to find new, possible medicines. We learned many things about **inclsiran** from this trial.



If you would like to **learn more**, ask a parent or another adult, or read the main summary for this trial at: www.novctrd.com

Search with the trial number
CKJX839C12301



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