

# Cholesterol-lowering jab could save over 30,000 lives

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- A new **heart disease drug** hailed as “life changing” has been approved for use in areas of the United Kingdom.
- The manufacturer, Novartis, and the National Health Service (NHS) of England and Wales struck a deal to offer the drug at a reduced cost.
- The decision came after a global trial showed that the drug can “safely cut cholesterol by 50%.”
- If 300,000 people receive the drug, as planned, a projected 30,000 people could avoid premature death due to **heart attacks** and **strokes**.

About half of the U.K.’s adult population currently has cholesterol levels above national guidelines, and almost 8 million people in the country are taking lipid-lowering drugs to combat this.

Now, a new drug already deemed a game changer could prevent 55,000 heart attacks and strokes in the U.K., saving more than 30,000 lives within the next decade.

The drug is called inclisiran, and it is administered as an injection. It boosts the liver’s ability to reduce levels of low-density lipoprotein (LDL) cholesterol, known as “bad” cholesterol.

**What does LDL (or “bad”) cholesterol do to the body?**

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Too much LDL cholesterol can lead to a buildup of fatty deposits called plaques in the blood vessels.

Over time, these deposits get larger and limit the flow of oxygen-rich blood to the heart. They may also suddenly break off and clog arteries or make them less flexible.

If these plaques cut off blood flow to the heart, it can lead to a heart attack. If this happens in an artery leading to the brain, it can cause a stroke.

The announcement of inclisiran's approval for use in England and Wales on Wednesday, September 1 came after months of negotiations between the NHS and the Swiss pharmaceutical company Novartis.

This followed the results of a global trial led by Imperial College London, which showed that the drug was highly effective.

**Phase 3 trials showed that when administered 6 months apart, inclisiran lowered cholesterol levels by up to 50%.**

The deal represents a first-of-its-kind approach to population health management. It came after approval from the National Institute for Health and Care Excellence and an agreement with Novartis to lower the price.

While the discount is still undisclosed, Novartis normally prices a 284-milligram dose pack at around £2,000.

## **Why inclisiran is deemed 'life changing'**

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Inclisiran is the first treatment to employ RNA interference to help the body remove harmful cholesterol from the bloodstream.

It does this by silencing a gene called *PCSK9*, which instructs the body to produce a protein that helps regulate the amount of cholesterol in the blood. By turning off this gene, inclisiran helps the liver absorb more LDL cholesterol from the blood and break it down.

Inclisiran may also be a convenient, effective option for people who have not seen satisfactory reductions in their cholesterol levels with drugs called statins, as well as for people who cannot take this type of drug.

Furthermore, when inclisiran is combined with a statin, researchers predict a 75–80% reduction in cholesterol levels.

The under-the-skin jab will be administered by a nurse twice annually. The NHS says that for the time being, the new drug will be offered to people who have already experienced a heart attack or stroke and who have high cholesterol or a genetic disorder called mixed dyslipidemia, which results in high cholesterol.

A person can contact their general surgery for a prescription, it will be not be necessary to visit a hospital. *The Times* reports that the drug's rollout could start within a month.

## **Saving thousands of lives**

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If the rollout goes as planned, and 300,000 people receive the drug from the NHS within the next 3 years, 30,000 people could avoid heart attacks and strokes.

Prof. Sir Nilesh Samani, the medical director of the British Heart Foundation (BHF), said:

“The approval of inclisiran is good news for heart patients in the U.K. The twice-yearly injection to lower LDL, or ‘bad,’ cholesterol in patients with existing heart disease, whose cholesterol is not adequately controlled with statins or other drugs, will help to prevent people from having further heart attacks or strokes, ultimately maximizing the numbers of lives saved.”

Prof. Samani added that he hopes the cholesterol-busting drug will become available for a wider population.

“More research is needed to confirm the full extent of its benefits, but I anticipate that in the future, it will also be approved to lower cholesterol for a much wider group of people, to prevent them from having a heart attack or stroke in the first place.”

**Prof. Kausik Ray, the director of the Imperial Centre for Cardiovascular Disease Prevention, says that over the next 10 years, inclisiran will reduce the heart attack and stroke risk for people with high cholesterol and a history of heart disease from 29% to 20%.**

He also explains how inclisiran and statins can work together. “Statins and inclisiran are complementary. Statins make more cholesterol receptors, and inclisiran, by stopping the production of [the *PCSK9* protein] makes these receptors last or survive longer. The two treatments reduce LDL [cholesterol] by about 75–80%, when compared to no treatment.”

**A 50% annual reduction of LDL cholesterol in the population will translate to a 30% drop in cardiovascular events, Prof. Ray adds.**

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## Addressing misconceptions

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Dr. Derek Connolly, a consultant interventional cardiologist at Birmingham City Hospital, in the U.K., told *Medical News Today* that it was accurate to call the drug “life changing.”

The twice-yearly dosage means an easier and more convenient treatment plan, and the new drug will be “perfect for the statin-intolerant,” he said.

Though long-term data about the drug is not yet available, Dr. Connolly said he had no concerns.

Dr. Muhammed Keskin, an interventional cardiologist and associate professor of cardiology at Bahçeşehir University, in İstanbul, agreed: “The fact that it provides very effective LDL reduction in patients with resistant high cholesterol will ensure that the drug is preferred. [I]

do not think there is cause for concern because the side effect profile of the drug was found to be quite similar to [that of a] placebo.”

Dr. Keskin said inclisiran will likely gain acceptance quickly because there is already such a significant number of people with resistant high LDL cholesterol. “These patients were already using a molecule called ezetimibe or two other [*PCSK9*] inhibitors. So inclisiran may be preferred over the other two *PCSK9* inhibitors.”

Evolocumab and alirocumab are also used to inhibit *PCSK9* in people who cannot tolerate statins or have high LDL levels despite statin use. The two are classed as monoclonal antibodies, a type of biologic drug, and administered via injection every 2 weeks.

Dr. Keskin added that while the new drug is likewise a *PCSK9* inhibitor, it involves much newer technology, called small interfering ribonucleic acid: siRNA.

The biggest challenges now, according to Dr. Connolly, are to find people willing to try inclisiran and to convince healthcare professionals to prescribe it. “The problem is [that the] statin/vaccine denier community is already against this on principle. But if we can be as successful as the [COVID-19] vaccine rollout, we will save many lives.”

Dr. Keskin cautioned that studies so far have only examined the use of inclisiran in limited situations.

“The aim of the studies conducted was to treat patients who have high LDL despite using statins or those who cannot tolerate statins. Statins are still the first choice in cardiovascular diseases with high LDL cholesterol. The study did not include a population of patients who have never used statins,” he told *MNT*.

Another hurdle is the high price tag, which will limit access to and use of the drug, Dr. Keskin added.

The European Commission was the first to approve inclisiran for use in lowering LDL cholesterol, in December 2020. The Food and Drug Administration (FDA) has not yet approved it.

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