

# Meta-analysis confirms benefit of statins in those with no previous history of vascular disease

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Even people at low risk of heart problems would benefit from statins, cheap drugs that lower levels of ‘bad’ cholesterol in the blood.

That’s the main finding of a giant collaborative study coordinated by Oxford’s Clinical Trial Service Unit and the Health Economics Research Centre, and published in *The Lancet* today.

About half of deaths from cardiovascular disease occur in people with no previous history of the disease, so preventing such deaths can only be done by targeting seemingly healthy people. The new research shows that treating healthy people who are for some reason at increased risk of

disease would be effective, and safe, and it could see moves made toward offering these drugs to many millions of middle-aged people around the world, saving hundreds of thousands of lives.

"The study settles once and for all previous uncertainties about whether people at low-risk of heart disease – healthy, middle-aged people – would see benefits from taking statins," says Professor Colin Baigent, who led the study. There would be fewer 'events' such as heart attacks and strokes, and this would greatly outweigh risks of any side-effects of the drugs.

The study used data for 175,000 individual participants taking part in 27 different randomised trials of statins that on average ran for around 5 years. Well over 50,000 of those people included in the analysis were at low risk of heart disease, with this group experiencing around 2000 heart attacks, strokes or similar.

With the potential of statins to save many lives, low risks of known side-effects, and the cheap cost of the pills (now that generic versions have become available over recent years), the question now switches to what should the guidelines be: how low should your risk of heart problems be before your doctor starts prescribing these pills?

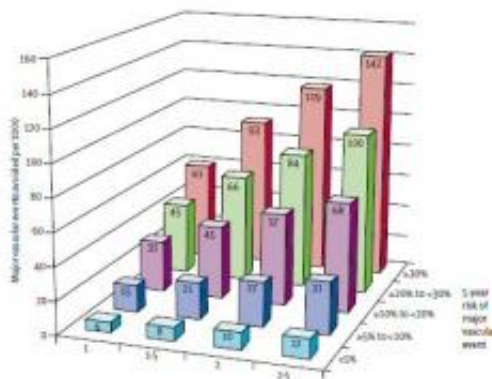
Colin puts it like this: 'To what extent should society spend resources on healthy people where there are small individual benefits but it offers the possibility of saving more lives across populations?'

"Should everyone get a statin? No. But where do you draw the line? GPs currently offer statins to people with a previous history of cardiovascular disease, and also to healthy people whose risk of such an event exceeds about 20% over 10 years. Our work suggests that we could save many more lives if we lowered that threshold, and we think that it would be sensible for NICE to review their recommendations in the UK to see

whether they agree."

Measures for preventing cardiovascular disease include encouraging healthy exercise, improving diet and stopping smoking, and all have their part to play in preventing these problems. But Colin emphasises that additional benefits are possible through wider use of statin therapy.

"Now we have these enormously beneficial tablets that our research shows could play an even greater role in an effective public health strategy," says Colin.



Statins are not just for people with high cholesterol, but may be appropriate for anyone who is at increased risk. "The emphasis has been on treating according to people's cholesterol levels," says Colin. "We need to get away from that focus on cholesterol levels in people's blood and instead think about their level of risk of cardiovascular problems. Our research shows that if a person has an increased risk of heart attacks, perhaps because they are overweight or a smoker, and yet have normal cholesterol levels, then that person would benefit if their

cholesterol was reduced to lower levels. It's a different way of thinking about it, because we have been encouraged to know our 'cholesterol level', whereas what we really need to know is our 'risk level', and we should base our decisions about whether to commence statin treatment on that information and not solely on cholesterol levels."

So what did the study published today in *The Lancet* do?

Colin explains: "We were interested in low-risk people and whether these very healthy people would still experience a benefit from taking statins. There had been controversy over whether there was a benefit of statins for those at low risk of heart attacks. Some studies suggested it didn't exist, some did.

"We used information recorded in the trials to set participants [all 175,000] in order of risk. We used measures like cholesterol level, blood pressure, whether or not someone was a smoker to calculate their risk of a heart attack or stroke. We worked out who had the lowest, who the highest and ordered them in line for every trial."

The researchers then grouped everyone into brackets of risk of having a major cardiovascular event over the course of five years, from those who had 30% risk at the other.

"Because we had all the data on heart attacks and strokes from the trials we could check the risk scores accurately described what happened," Colin explains.

Those in the bottom risk groups do come predominantly from six or seven of the 27 randomised trials included in the analysis. But Colin says including all people from all the trials meant they didn't just look at those trials that set out to look at low-risk healthy people, they looked at all the available data.

And the results across all risk groups were comparable: Those with low risk of heart events see similar proportional reductions in heart problems to those at much greater initial risk.

But those with a much bigger risk to begin with would see a larger drop in risk, so it's important to look at the absolute figures.

The researchers estimate that for every 1000 largely healthy people (less than a 10% risk of heart problems over five years) lowering their 'bad' cholesterol levels by 1 mmol/litre through taking statins (a fair outcome of statin therapy, stay with me), there would be 11 fewer heart attacks or strokes over a 5 year period. That's perhaps hard to work through what those numbers mean. It's perhaps not a huge change for each individual.

But would add up to many heart attacks, strokes, and deaths prevented in healthy people if lots of people were taking the pills.

A better way of looking at these numbers is probably visually. A figure at the end of the Lancet paper makes clear the number of heart attacks and strokes avoided through taking statins. There are many more heart events prevented in the high risk groups, of course. But the benefits do extend right the way to the bottom, with measurable bars still appearing for the much larger population of people at very low risk of heart problems only lowering their bad cholesterol by a bit.

In taking any drug there is the potential for side-effects, and when so many people are taking statins, these are important to consider even if they occur at low rates.

There are a number of known side-effects of statins but these are uncommon and the beneficial effects in terms of preventing heart attacks and strokes greatly exceed the small risks, even among those at very low risk. "These are very safe drugs," emphasises Colin.

Statins can cause muscle problems, and problems in the liver – though these reverse on stopping taking the pills. Recently, statins have been linked with an increased risk of bleeding in the brain. These are rare, unusual but real side-effects, the evidence shows. Statins may also increase the risk of developing diabetes, but the cardiovascular benefits of statins in low-risk people are substantial even after allowing for this increase in diabetes.

That's very reassuring when hearing stories of people experiencing muscle pain after starting statins. Some of these may not be connected to the statin and may have happened anyway. But without evidence like this it is certainly harder to compare these tales of side-effects against the heart attacks that didn't happen, where there is no tale to be told.

**More information:** Paper online: [www.thelancet.com/journals/lan ... \(12\)60367-5/abstract](http://www.thelancet.com/journals/lan... (12)60367-5/abstract)

Provided by Lancet

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