

New study suggests benefit-to-harm balance of statins for healthy adults 'generally favorable'

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Statins are associated with a small increased risk of side effects in patients without a history of heart disease, but these effects are mild

compared with the potential benefits of treatment in preventing major cardiovascular events, say researchers in *The BMJ* today.

They say their findings suggest that the benefit-to-harm balance of statins for adults without heart disease is generally favorable.

Statins are widely used to prevent heart disease, and [severe side effects](#) are rare, but many people are reluctant to take them because of the potential for milder effects such as [muscle weakness](#) and stiffness.

For people with existing heart disease, the benefits of statins far outweigh the risk of these effects, but when statins are used by people without a history of heart disease (known as [primary prevention](#)) the benefit-to-harm balance of treatment might be less favorable.

Yet recent guidelines have recommended wider use of statins for primary prevention.

So, a team of UK and US researchers set out to examine the associations between statins and adverse events in adults without a history of [heart disease](#), and how they vary by type and dose of statins.

They analyzed the results of 62 randomized controlled trials with 120,456 participants (average age 61; 40% women) followed up for an average of 3.9 years. The trials were designed differently, and were of varying quality, but the researchers were able to allow for that in their analysis.

Statins were associated with a slightly increased risk of self-reported muscle pain, liver and kidney problems, and certain eye conditions such as cataracts, but were not associated with clinically confirmed muscle disorders or diabetes.

These risks equated to 15 more instances of muscle symptoms, eight more liver events, 12 more kidney events, and 14 more eye conditions per 10,000 patients treated for a year.

However, these increased risks did not outweigh the reduction in the risk of major cardiovascular events. For example, statins were estimated to prevent 19 [heart](#) attacks, nine strokes, and eight deaths from cardiovascular disease per 10,000 patients treated for a year.

This suggests that the benefit-to-harm balance of statins for primary prevention of cardiovascular disease is favorable, say the researchers.

Analyses by type of [statin](#) showed that atorvastatin, lovastatin, and rosuvastatin were associated with some adverse events, but few significant differences were seen between the statins.

A possible modest dose-response relationship was identified for the effect of atorvastatin on liver dysfunction, but the dose-response relationships for the other types of statins and adverse effects were inconclusive.

This suggests that tailoring statin doses to deal with safety concerns when starting treatment is not currently needed, the researchers add.

This was a large study that was able to accurately assess the adverse effects of treatment with statins. But the researchers point to some limitations in trial design that may have led to events being underestimated or more severe long term events being missed.

However, they say the low risk of adverse events caused by statins reported in this review "should reassure patients and physicians that the potential harms of statins are small and should not deter their use for primary prevention of cardiovascular [disease](#)."

They agree that routine monitoring of liver function during treatment is probably warranted in primary prevention, and say further studies are needed to help improve adherence to treatment and achieve more efficient monitoring.

More information: Associations between statins and adverse events in primary prevention of cardiovascular disease: systematic review with pairwise, network, and dose-response meta-analyses, *The BMJ*, DOI: [10.1136/bmj.n1537](https://doi.org/10.1136/bmj.n1537)

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