Trial finds no overall effect of statins on muscle pain

February 24 2021

Credit: Pixabay/CC0 Public Domain

A trial published by *The BMJ* today finds no overall effect of statins on the frequency or severity of muscle symptoms compared with placebo in people who had previously reported severe muscle symptoms when

taking statins.

Most people completing the trial planned to restart treatment with statins.

Statins are widely used to prevent heart disease and stroke and while severe side effects are rare, many people believe that statins can cause muscle pain and stiffness, even though there is no clear clinical trial evidence to support this.

This belief has led to patients stopping treatment, exposing them to an increased risk of serious heart problems.

To address this uncertainty, a team of UK researchers set out to establish the effect of statins on muscle symptoms in people who had previously reported muscle symptoms when taking statins.

Their findings are based on 200 patients (average age 69.5 years) from 50 general practices in England and Wales who had recently stopped or were considering stopping treatment with statins because of muscle symptoms.

Each patient was part of an individual randomised, placebo controlled trial (known as an n-of-1 trial). When combined, the results can be used to assess the overall effect of a treatment.

Patients who participated were randomly assigned to a sequence of six, two-month treatment periods during each of which they received either statins or a placebo. Neither patients, nor their GP knew which tablet they were receiving.

Adherence to the study drug treatment was high, with at least 80% of participants reporting taking their drug treatment "every day" or "most

days" during each period.

At the end of each treatment period, participants rated their muscle symptoms, defined as pain, weakness, tenderness, stiffness, or cramp of any intensity, on a 0-10 point scale.

Overall, the researchers found no difference in muscle symptom scores between the statin and placebo periods.

They also found no differences for the effect of muscle symptoms on aspects of daily life (general activity, mood, ability to walk, normal work, relationships with other people, sleep, and enjoyment of life) between the statin and placebo periods.

Withdrawals because of intolerable muscle symptoms were 18 participants (9%) during a statin period and 13 (7%) during a placebo period.

Two thirds of those completing the trial said they planned to restart long term treatment with statins.

The researchers point out that they only assessed the effect of one type of statin on muscle symptoms, and that for some patients, pain scores may have been affected by treatment from the previous period.

However, they say this was a large, well-designed trial based on repeated measurements of muscle pain in patients who had experienced symptoms during statin treatment, allowing differences between statins and placebo to be assessed with greater accuracy.

They also suggest that muscle aches and pains are common among the age group taking statins and might occur coincidentally with the use of statins, leading patients and clinicians to erroneously attribute pain to

statins.

As such, they say this type of trial could be adopted by clinicians who are looking to establish the best course of treatment for patients, in general practice or outpatient settings, who present with muscle symptoms associated with statins.

Future work could focus on conducting n-of-1 trials for other types of statins and higher doses, and for other drugs which are associated with transient adverse effects, they conclude.

More information: Statin treatment and muscle symptoms: series of randomised, placebo controlled n-of-1 trials, *BMJ* (2021). DOI: 10.1136/bmj.n135

Provided by British Medical Journal