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LETTERS

STATIN SIDE EFFECTS STUDY

Meta-analysis of side effects of statins shows need for trial transparency

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As Wise reported,[1] our meta-analysis looked at side effects in randomised trials of statins and found that many, such as muscle aches, were reported to an equal degree by participants taking a placebo. Those side effects may therefore be partly non-pharmacological, and due to negative expectations, or the "nocebo" effect, as has been shown in research on other drugs.[2-4] For treatments where sufficiently large numbers of participants have been randomised, trials can potentially give more accurate information than observational studies on side effects.

Unfortunately, although our methods were sound, the reliability of our findings is probably undermined by the poor reporting of side effects in clinical trials reports in academic journals, as discussed in our paper. Of particular interest is a study by IQWiG, the German government's cost effectiveness agency, which was published after our study was conducted. It found on average that complete information was given for 87% of adverse event outcomes in the clinical study report (the standard lengthy regulatory document for industry trials), but for only 26% of adverse event outcomes in the academic journal publication.[5]

This is one more reason why the AllTrials.net campaign asks for all trials to be registered, with their full methods and results reported, including the clinical study report, if one has been created. We cannot help patients make informed decisions about the risks and benefits of treatments until this information is routinely shared with doctors, researchers, and patients.[6 7]

Competing interests: I am a co-author on the paper in question, and co-founder of the AllTrials.net campaign for transparency in clinical trials.

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