Medical Research Council Media Release

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Aspirin in primary prevention: overall benefit is uncertain

A new study has shown that, whilst taking aspirin is beneficial in preventing heart attacks and strokes among people with established cardiovascular disease (secondary prevention), its benefits don't clearly outweigh the risks of bleeding in healthy people (primary prevention). Researchers at the Clinical Trial Service Unit at the University of Oxford analysed data from a number of primary and secondary prevention trials that had compared long term aspirin use versus control.

The research, led by Medical Research Council scientist Professor Colin Baigent and published in *The Lancet* today, found that, in the primary prevention trials, aspirin reduced the risk of non-fatal heart attack by about one fifth, corresponding to 5 fewer such episodes each year for every 10,000 people treated, but this was offset by a comparable increase in bleeds (i.e. 1 extra stroke caused by bleeding and 3 extra gastrointestinal bleeds each year per 10,000 treated). There was no difference in stroke or in death. In the secondary prevention studies, where the risk of an event was much higher, aspirin reduced the risk of a serious vascular event (a heart attack, stroke or cardiovascular death) by about a fifth, so that there were 150 fewer such events each year for every 10,000 patients treated. This large benefit greatly exceeded the risk of bleeding. In both sets of trials, the risk of a serious vascular event was reduced to a similar degree in both men and women.

Previous reviews of primary prevention trials have led to guidelines recommending that aspirin be used widely for primary prevention among healthy people who, for some reason (e.g. raised blood cholesterol or blood pressure), are at above average risk of coronary heart disease and therefore might be expected to benefit more than others. But the new analyses show that many people with above average risk of coronary heart disease are also at above average risk of suffering a bleed, so this method of selecting whom to treat may not be appropriate.

Professor Baigent said: "The primary prevention trials were completed some years ago, when modern drugs such as statins were not widely available. Nowadays, primary prevention with statins and other drugs can safely half the risk of heart attacks and strokes. When aspirin is added to such drugs, the further reduction in serious vascular events is only about half as large as when it is used alone, but the bleeding risks will remain about the same. This has important implications when judging the likely effects of aspirin in practice."

The authors conclude: ''Aspirin is of clear benefit for people who already have cardiovascular disease, but the latest research does not seem to justify general guidelines advocating the routine use of aspirin in all healthy individuals above a moderate level of risk for coronary heart disease.''

When prescribing aspirin to healthy individuals, it is important to consider the potential of such a policy to cause harm. Professor Baigent added: "Drug safety really matters when making recommendations for tens of millions of healthy people. We don't have good evidence that, for healthy people, the benefits of long-term aspirin exceed the risks by an appropriate margin."

Notes to Editors

"Aspirin in the primary and secondary prevention of vascular disease: collaborative meta-analysis of individual participant data from randomised trials" is published in *The Lancet.*

For further information please contact the Medical Research Council press office on 020 76376011 or press.office@headoffice.mrc.ac.uk Out of hours please call: 07818 428 297.

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