A randomised, double-blind, placebo-controlled study to evaluate the efficacy of oral azithromycin as a supplement to standard care for adult patients with acute exacerbations of asthma (the AZALEA trial)

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Plain English summary

The AZALEA trial

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Plain English summary

Acute asthma attacks are common and cause substantial suffering and, occasionally, death. Current treatments for asthma attacks are not as effective as they should be and new/better treatments are needed. Viral chest infections often cause asthma attacks and bacterial chest infections have also been associated with some attacks. However, current guidelines recommend that antibiotic therapy should *not* routinely be given, as a role for bacteria is uncertain. We previously reported that adults experiencing asthma attacks showed a significantly greater reduction in symptoms and faster recovery when given the antibiotic telithromycin compared with placebo ('dummy' treatment). However, safety concerns have limited the use of telithromycin. We therefore investigated whether or not azithromycin, which is similar to telithromycin, might be of benefit in asthma attacks through having an antibacterial, antiviral or anti-inflammatory effect. In addition, we looked at (1) how frequently bacteria are detected in asthma attacks and (2) whether or not those people with a bacterial infection recovered better from an asthma attack. We recruited 199 patients into the study from 31 different centres. We could not demonstrate a statistically significant difference between the azithromycin group and the placebo group in patient diary scores or in any pulmonary function tests. There were no differences between groups in time to recovery. The numbers of bacterial infections were low and there was no suggestion of a treatment benefit in subjects with detectable bacteria.

For every patient randomised to treatment, approximately 10 other patients were not eligible to be included as they had already received antibiotic therapy. Conclusions were limited because not enough people participated in the trial.

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