



Synopsis

Azithromycin therapy for prevention of chronic lung disease of prematurity (AZTEC): a randomised placebo-controlled trial

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†In memoriam

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Plain language summary

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Why did we do this study?

Many premature babies will develop a disease called chronic lung disease of prematurity during their stay in hospital. Chronic lung disease of prematurity develops due to the impact of additional oxygen and breathing support given to help the babies' lungs, which are too immature to work independently. We and several research groups have shown that infection and inflammation are increased in babies who develop chronic lung disease of prematurity. Chronic lung disease of prematurity can lead to more hospital admissions in infancy and breathing problems during childhood and beyond. Azithromycin is an antibiotic which has been shown to treat both lung infections (particularly a bacteria called *Ureaplasma*) and inflammation and might reduce the number of babies who develop chronic lung disease of prematurity. So, we planned the azithromycin therapy for prevention of chronic lung disease of prematurity trial to assess if 10 days of azithromycin treatment improved rates of survival without chronic lung disease of prematurity in prematurely born babies when compared to a placebo (dummy) medicine.

What did we do?

Between October 2019 and March 2022, we enrolled 799 babies in the trial. Approximately, half received azithromycin, and half received placebo. We assessed how many babies developed chronic lung disease of prematurity in each group. We also took respiratory samples to look for infections (particularly, *Ureaplasma*). Poo samples were taken to look at whether giving azithromycin increased resistance to antibiotics which might impact on how effective other common treatments are.

What did we find?

We found that treatment with azithromycin, although apparently safe, did not change rates of chronic lung disease of prematurity compared to the placebo medicine. Our findings mean that we cannot recommend its use in premature babies to improve breathing outcomes. Also, we found that carriage of antibiotic resistant genes in poo and lung secretions in babies increased over babies' stay in hospital when they received azithromycin.

What does this mean for premature babies with chronic lung disease of prematurity?

The results mean that premature babies should not routinely be given azithromycin early after birth as an additional medicine to help with their breathing. Since premature babies may need many medicines for their care, this trial provides useful information for healthcare professionals involved in their management. Researchers will need to look at other options for improving outcomes for breathing problems, which might include combinations of medicines or other therapies.