



## Synopsis

# A pragmatic, multicentre, placebo-controlled, 3-arm, double-blinded, randomised controlled trial, incorporating an internal pilot, to determine the role of bronchodilators in preventing exacerbations of bronchiectasis

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## Plain language summary

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## Plain language summary

Bronchiectasis is a long-term lung condition. People with it cough more, make more mucus, have shortness of breath and repeated chest infections (flare-ups). Reducing the number of flare-ups is key for patients, but there is no inhaled medication approved specifically to treat bronchiectasis. Instead, treatments given are ones used to treat other lung conditions.

This trial aimed to see if two different types of inhalers, dual therapy and triple therapy, reduce flare-ups. Dual therapy contains two medicines that help to open up airways and make breathing easier. Triple therapy contains these same two medicines and a medicine to reduce inflammation. These inhalers were compared to a 'dummy' or placebo inhaler that contains no medicine.

Which inhaler participants took was decided by a computer at random. All inhalers were identical, and participants and their doctors did not know which one they were taking. One puff of the inhaler was taken once a day for 12 months. Patients were recruited from nine United Kingdom National Health Service hospitals, but not at the rate expected. When 33 participants were recruited instead of the 120 expected at that time point, the trial was closed early because of slow recruitment. The COVID-19 pandemic had a big impact. It meant that hospitals had longer timelines due to setting up the trial and less staff available. Patients were shielding and worried about visiting hospitals.

Results show that 14 participants took dual therapy, 12 took triple therapy and 7 took placebo. On average, participants taking dual or triple therapy had less flare-ups and had more time to having their first flare-up than those taking placebo. Though we cannot make firm conclusions because of the small number of participants, the results highlight the importance of completing a large-scale trial of these therapies to help improve understanding of the best treatment for bronchiectasis.