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## Covid-19: Budesonide shortens recovery time in patients not admitted to hospital, study finds

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Inhaled budesonide, a common corticosteroid used to treat asthma and chronic obstructive pulmonary disease, can shorten the time it takes for people not admitted to hospital to recover from covid-19 by three days, a trial in people over 50 at greater risk of covid-19 and people aged over 65 has found.

As part of the Principle trial, 961 people were randomly assigned to receive inhaled budesonide at home and were compared with 1819 patients randomly assigned to the usual standard of NHS care alone.

The interim analysis, based on data collected up to 25 March 2021, involved 751 people in the budesonide group (800 µg twice a day for 14 days) and 1028 in the usual care group who were SARS-CoV-2 positive. It found that the median time to self-reported recovery for people taking inhaled budesonide was 3.011 days shorter compared with usual care (95% Bayesian credible interval 1.134 to 5.410 days), with a high probability (0.999) of being superior to the usual standard of care.

Around one third (32%) of people taking inhaled budesonide recovered in the first 14 days post-randomisation and remained well until 28 days, compared with just over one fifth (22%) in the usual care group. The budesonide group also reported greater wellbeing after two weeks (mean difference in WHO-5 wellbeing score +3.37, 95% confidence interval 0.97 to 5.76,  $P=0.006$ ).

Looking at hospital admissions, the researchers reported that of those who had completed all 28 days of study by the cut off date, 8.5% (59 of 692) in the budesonide group were admitted to hospital with covid-19 compared with 10.3% (100 of 968) in the usual care group (estimated percentage benefit, 2.1% (95% BCI -0.7% to 4.8%), probability of superiority 0.928).

Since fewer than expected people were admitted to hospital in the trial, however, and as covid-19 cases and hospital admissions were dropping in the UK, the researchers said it was not clear whether budesonide reduced hospital admissions.

Fiona Watt, executive chair of the Medical Research Council, which co-funded the study, said, “Researchers involved in the Principle trial have overcome considerable logistical hurdles to set up a world leading rigorous drug trial in people’s homes. We are now rewarded with the first inexpensive and widely available drug that can shorten recovery times for covid-19 patients in the community.”

Joint chief investigator Chris Butler, a south Wales GP and professor of primary care from the University of Oxford, said, “We therefore anticipate that medical practitioners around the world caring for people with covid-19 in the community may wish to consider this evidence when making treatment decisions.”

The results will be published once all remaining trial participants have completed the follow-up and the full analysis has been completed. The Principle study is funded by UK Research and Innovation and the Department of Health and Social Care.

The UK government said in a statement that budesonide was “not currently being recommended as standard of care but can be considered (off label) on a case-by-case basis for symptomatic covid-19 positive patients aged 65 and over, or aged 50 or over with co-morbidities.”