RAPID C-19 OVERSIGHT GROUP

Summary briefing

Budesonide

16 September 2021

# Background

* This briefing lists the evidence the RAPID C-19 oversight group used to assess whether budesonide can be used as a potential treatment for COVID-19.
* Budesonide is a corticosteroid with anti-inflammatory properties. It is licensed in the UK for treating asthma.
* The RAPID C-19 oversight group continues to monitor the emerging evidence.

# Evidence

This section lists only the publicly available evidence when the oversight group last reviewed budesonide, in August 2021. Information provided in confidence by trial sponsors, companies and investigators is not included.

## PRINCIPLE (2020-001209-22)

### Study details and population

PRINCIPLE is a UK multicentre, open-label, adaptive platform randomised controlled trial. It included adults in the community at high risk of COVID-19 complications who were:

* at least 65 years or at least 50 years with comorbidities
* unwell for up to 14 days with suspected or confirmed COVID‑19.

Trial treatments were inhaled budesonide 800 micrograms twice daily for 14 days plus usual care (n=1,073), usual care alone (n=1,988) or usual care plus other treatments (n=1,639).

### Results

Inhaled budesonide improves time to recovery and may also reduce hospital admissions or deaths in this population.

The results are available in the peer-reviewed publication: [Inhaled budesonide for COVID-19 in people at high risk of complications in the community in the UK (PRINCIPLE): a randomised, controlled, open-label, adaptive platform trial](https://www.sciencedirect.com/science/article/pii/S014067362101744X?via%3Dihub).

## STOIC (NCT04416399)

### Study details and population

STOIC is a UK phase 2, open-label randomised controlled trial in adults in the community with confirmed mild COVID-19 symptoms (n=146). People had inhaled budesonide 800 micrograms twice daily for a median of 7 days (n=73), or usual care (n=73).

### Results

Early administration of inhaled budesonide reduced the likelihood of needing urgent medical care and reduced time to recovery after early COVID-19.

The results are available in the peer-reviewed publication: [Inhaled budesonide in the treatment of early COVID-19 (STOIC): a phase 2, open-label, randomised controlled trial](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600%2821%2900160-0/fulltext#seccestitle10).

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