

Trial Arm Inclusion and Exclusion Criteria

Trial Arm	Inclusion	Exclusion
Criteria that applies to all trial arms	<p>1. Participant or their legal representative, is willing and able to give informed consent for participation in the study, and is willing to comply with all trial procedures</p> <p>2. Suspected COVID-19 using the NHS syndromic definition, OR symptoms* consistent with COVID-19 and with a positive test for SARS-CoV-2 infection within the past 14 days</p> <p>3. Symptoms must have started within the past 14 days and be ongoing</p> <p>AND Age criteria as specified according to each treatment arm</p>	<ul style="list-style-type: none"> • Patient currently admitted in hospital • Almost recovered (generally much improved and symptoms now mild or almost absent) • Judgement of the recruiting clinician deems ineligible. • Previous randomisation to an arm of the PRINCIPLE trial
Usual Care	<p>Criteria which applies to all, in addition to:</p> <p>Participant is aged 65 or over OR Participant is aged 18- 64, and is experiencing shortness of breath** as part of COVID-19 illness OR Participant is aged 18-64 and has any of the following underlying health conditions:</p> <p>a) Known weakened immune system due to a serious illness or medication (e.g. chemotherapy); b) Known heart disease and/or a diagnosis of high blood pressure c) Known chronic lung disease (e.g. asthma) d) Known diabetes e) Known mild hepatic impairment;</p>	<ul style="list-style-type: none"> • As above, criteria that applies to all arms

	<p>f) Known stroke or neurological problem; g) Self-report obesity or body mass index ≥ 35 kg/m²</p>	
Colchicine + Usual Care	Same criteria as for usual care	<p>Criteria which applies to all arms, in addition to:</p> <ul style="list-style-type: none"> • Hypersensitivity to the active substance or to any of the excipients listed in section (Lactose, Pregelatinised Maize Starch, Stearic Acid, Purified Talc, Purified Water, Ethanol 96%) • Known or suspected pregnancy • Breastfeeding • Women of childbearing potential (premenopausal female that is anatomically and physiologically capable of becoming pregnant*) and not prepared to use highly effective contraception for the 28 day duration of follow up in the study • Known blood dyscrasias • Known severe renal impairment or requiring dialysis • Known severe hepatic impairment • Currently taking any of the following: colchicine, clarithromycin, erythromycin, ketoconazole, itraconazole, voriconazole, HIV protease inhibitors (e.g. ritonavir, atazanavir), cobicistat, verapamil, diltiazem, cyclosporin, quinidine, disulfiram, grapefruit juice • Inflammatory bowel disease or chronic diarrhoea
Budesonide + Usual Care	Criteria which applies to all, in addition to:	<p>Criteria which applies to all arms, in addition to::</p> <ul style="list-style-type: none"> • A known allergy to inhaled corticosteroids

	<p>Patients aged ≥65 years, or Patients aged 50-64 years and meeting at least one of the following criteria:</p> <ul style="list-style-type: none"> • Known weakened immune system due to a serious illness or medication (e.g. chemotherapy); • Known heart disease and/or a diagnosis of high blood pressure; • Known asthma or lung disease; • Known diabetes; • Known mild hepatic impairment; • Known stroke or neurological problem; • Self-report obesity or body mass index ≥35 kg/m² 	<ul style="list-style-type: none"> • Any known contraindication to inhaled corticosteroids (as per SmPC, <i>patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Lactose, the excipient in the product, contains small amounts of milk proteins and can therefore cause allergic reactions</i>). • Patient currently prescribed inhaled or systemic corticosteroids • Unable to administer inhaler
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** These symptoms may include, but are not limited to, shortness of breath, general feeling of being unwell, muscle pain, diarrhoea and vomiting.*

*** Shortness of breath has been described in the Participant Information Sheet as the following: Shortness of breath can make it hard to breathe deeply and you may feel winded or as if you can't get enough air into your lungs. Unlike many other conditions that can cause shortness of breath, this symptom can persist and quickly escalate in people with COVID-19.*