

Randomisation Program

Call Freefone 0800 138 5451 to contact the RECOVERY team for URGENT problems using the Randomisation Program or for medical advice. All NON-URGENT queries should be emailed to recoverytrial@ndph.ox.ac.uk

Logged in as: RECOVERY Site

Section A: Baseline and Eligibility

Date and time of randomisation: 22 Feb 2021 14:00

Treating clinician
A1. Name of treating clinician

Patient details
A2. Patient surname
Patient forename
A3. NHS number Tick if not available
A4. What is the patient's date of birth? / /
A5. What is the patient's sex?

Inclusion criteria
A6. Has consent been taken in line with the protocol?
If answer is No patient cannot be enrolled in the study
A6.1 Has consent been given for the early phase assessment of dimethyl fumarate? Yes
A6.2 Has S/F₉₄ been measured according to the SOP? Yes
A7. Does the patient have proven or suspected SARS-CoV-2 infection?
If answer is No patient cannot be enrolled in the study
A8. Does the patient have any medical history that might, in the opinion of the attending clinician, put the patient at significant risk if they were to participate in the trial?
A9. COVID-19 symptom onset date: / /
A10. Date of hospitalisation: / /
A11. Does the patient require oxygen?
A12. Please select one of the following to describe the current level of ventilation support
A12.1 Enter latest oxygen saturation measurement (%)
A12.2 Enter latest CRP measurement since admission to hospital (mg/L) Tick if not measured
Enter 0 if below the limit of measurement Tick if greater than limit of measurement
A12.3 Enter latest creatinine measurement since admission to hospital (µmol/L) Tick if not measured
A12.4 Enter latest D-dimer measurement since admission to hospital (ng/mL) Tick if not measured
Enter 0 if below the limit of measurement Tick if greater than limit of measurement
A12.5 Has the patient received a COVID-19 vaccine?

Does the patient have any CURRENT comorbidities or other medical problems or treatments?
A13.1 Diabetes
A13.2 Heart disease
A13.3 Chronic lung disease
A13.4 Tuberculosis
A13.5 HIV
A13.6 Severe liver disease
A13.7 Severe kidney impairment (eGFR <30 or on dialysis)
A13.8 Known long QT syndrome
A13.9 Current treatment with macrolide antibiotics which are to continue
Macrolide antibiotics include clarithromycin, azithromycin and erythromycin
A13.10 Antiplatelet therapy
Includes aspirin, clopidogrel, ticagrelor, prasugrel, dipyridamole
A13.12 Has received tocilizumab therapy during this admission

**Are the following treatments UNSUITABLE for the patient?
If you answer Yes it means you think this patient should NOT receive this drug.**
A14.3 Colchicine
NB Colchicine is NOT suitable if patient (i) is pregnant; (ii) has severe hepatic impairment; (iii) has significant cytopenia; (iv) is on strong CYP3A4 or P-gp inhibitor; or (v) is hypersensitive to lactose. See protocol for more details.
A14.4 Dimethyl fumarate
NB Dimethyl fumarate is NOT suitable if patient is pregnant or breastfeeding No
A14B.1 Synthetic monoclonal antibodies (REGN10933+REGN10987)
A14C.1 Aspirin
A14D.1 Baricitinib
NB Baricitinib is NOT suitable if patient (i) is pregnant; (ii) has eGFR <15 mL/min or is on dialysis/haemofiltration; (iii) has active TB; or (iv) has neutrophil count <0.5

Are the following treatments available?
A15.3 Colchicine
A15.4 Dimethyl fumarate Yes
A15B.1 Synthetic monoclonal antibodies (REGN10933+REGN10987)
A15C.1 Aspirin
A15D.1 Baricitinib

Current medication
A16.1 Is the patient currently prescribed remdesivir?
A16.2 Is the patient currently prescribed systemic corticosteroids (dexamethasone, prednisolone, hydrocortisone, methylprednisolone)?
Please do not include topical or inhaled treatments
A16.4 Is the patient currently on warfarin or a direct oral anticoagulant?
Includes apixaban, rivaroxaban
A16.5 What venous thromboembolism prophylaxis is the patient receiving?
Standard = usual for hospitalised patients (not increased due to COVID-19); Higher dose = treatment dose or increased prophylaxis due to COVID-19

**A17.2 Early phase assessment of dimethyl fumarate: S/F₉₄ measurement
This participant is eligible for this part of RECOVERY. Please enter their current S/F₉₄ (refer to SOP for instructions on measurement).**
A17.2.1 Oxygen delivery mode
A17.2.2 Inspired oxygen concentration (FiO₂) (%)
A17.2.3 High-flow nasal oxygen flow rate
A17.2.4 Peak end-expiratory pressure (PEEP) (cm H₂O)
A17.2.5 Peripheral oxygen saturation (SpO₂) (%)
A17.2.6 Respiratory rate (breaths per minute)

Please sign off this form once complete
Surname:
Forename:
Professional email: