Early Safety Data

This form should NOT be completed less than 72 hours after randomisation (unless the patient has been discharged or died)

Patient's date of birth *

yyyy-mm-dd

Convalescent Plasma

1. How many convalescent plasma infusions did the patient receive? *

This is plasma given as part of a trial, not any standard fresh frozen plasma or other blood products that the patient may have been given

◯ 0 ◯ 1 ◯ 2

A patient is not expected to receive both a convalescent plasma and a synthetic monoclonal antibodies infusion. Please check your answers.

1.1. Were any infusions stopped early for any reason ie, the patient did not receive the full amount?

◯ Yes ◯ No

1.2. How many were stopped early?

◯ 1 ◯ 2

Synthetic monoclonal antibodies (REGN10933+REGN10987)

1.B. Did the patient receive an infusion of REGN10933+REGN10987? *

◯ Yes ◯ No

A patient is not expected to receive both a convalescent plasma and a synthetic monoclonal antibodies infusion. Please check your answers.

Date infusion started

yyyy-mm-dd

Time infusion started

(hh:mm [24 hr])

The infusion should not start before randomisation. Please check your answers.

The infusion is expected to start within 48 hours of randomisation. Please check your answers.

1.B.1. Was the infusion stopped early for any reason ie, the patient did not receive the full amount?

Yes No

1.B.2. Did the patient have a reaction during the infusion?

Yes No

1.B.3. How was the reaction managed?

Please tick all that apply

- [ ] No intervention required
- [ ] Infusion rate reduced, but infusion completed
- [ ] Antihistamine given
- [ ] Steroid given
- [ ] Adrenaline given
- [ ] Infusion stopped early

First 72 hours after the first randomisation

2. During the first 72 hours after the first randomisation has the patient had any of the following?

2.1. Sudden worsening in respiratory status *

Yes No Unknown

Please indicate the respiratory support delivered

Please tick all that apply

- [ ] No additional support
- [ ] New use or increased concentration of oxygen
- [ ] New use of non-invasive respiratory support (CPAP, BiPAP, HFNO)
- [ ] New use of invasive mechanical ventilation
- [ ] Other

Please provide details

Persistent change

Please indicate if persistent change (ie, increased support still required at 72 hours)

2.2. Severe allergic reaction *

Yes No Unknown

Please indicate if adrenaline was required?

◯ Yes ◯ No

2.3. Temperature >39˚C or ≥2˚C rise above baseline *

◯ Yes ◯ No ◯ Unknown

2.4. Sudden hypotension *

Defined as either (i) sudden drop in systolic blood pressure of ≥30 mmHg with systolic blood pressure ≤80 mmHg; or (ii) requiring urgent medical attention

◯ Yes ◯ No ◯ Unknown

Please indicate support given

Please tick all that apply

☐ No support required

☐ New or additional intravenous fluid

☐ New or additional inotropic/vasopressor support

Persistent change

◯ Please indicate if persistent change (ie, increased support still required at 72 hours)

2.5. Clinical haemolysis *

Defined as fall in haemoglobin plus one or more of the following: rise in lactate dehydrogenase (LDH), rise in bilirubin, positive direct antiglobulin test (DAT), or positive crossmatch

◯ Yes ◯ No ◯ Unknown

Haemoglobin

◯ Please indicate if the lowest haemoglobin <100 g/L

Bilirubin

◯ Please indicate if the highest bilirubin >50 µmol/L

2.6. Thrombotic event *

Defined as either (i) acute pulmonary embolism; or (ii) deep-vein thrombosis; or (iii) ischaemic stroke; or (iv) myocardial infarction; or (v) systemic arterial embolism

◯ Yes ◯ No ◯ Unknown

Please indicate the type of thrombotic event

Please tick all that apply

☐ Acute pulmonary embolism

☐ Deep-vein thrombosis

☐ Ischaemic stroke

☐ Myocardial infarction

☐ Systemic arterial embolism

☐ Other

Please provide details

2.7. Was a SHOT report submitted?

Yes No Unknown

3. Please enter any additional information