

Convalescent Plasma Safety

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

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

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