

Report Overview - GB-MHRA-ESUSAR-215840423001-00108119

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 19/01/2021

1. Trial Information

- Reference: RECOVERY SUSAR 004
- Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

2. Patient Details

- Patient gender: Female
- Patient age at time of the side effect: 43 Years
- Patient Identification Number: 1279245

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
18/01/2021

Country of Origin:
United Kingdom

Narrative:

Previously fit and well. Presented to hospital on 9/1/2021 with increasing shortness of breath and discharged with clarithromycin and rivaroxaban. No further notes available. Presented to different hospital on 10/1/2021 with ~4 days of shortness of breath, fever and cough, tested positive for SARS-CoV-2 in the community. Admitted to intensive care from Emergency Department following an arterial blood gas with PaO₂ 7.7kPa on 15L non-rebreath mask. Started on continuous positive airway pressure. Patient remained very tachypnoeic so intubated and ventilated on 10/1/2021 and prone. 3 days of proning with good response. Non-clinical transfer from to tertiary centre (for bed management) on 13/01/2021. Uneventful extubation on 14/01/21. However 30mins to one hour after receiving first dose of RECOVERY REGN-COV2 monoclonal antibodies, patient was observed to have a tonic-clonic seizure lasting 1 minute. Subsequently reintubated. Levetiracetam subsequently started to provide prophylaxis against further seizure activity. Successful re-extubation 16/01/21. No further episodes of seizure activity observed, and levetiracetam subsequently stopped 17/01/21. Noradrenaline successfully weaned to off as of 17/01/21. RECOVERY informed on 18/01/2021 when local investigator became aware of event.

Seriousness

- Hospitalisation

Seizure

- Reaction Outcome: Recovered
- Start date: 14/01/2021

‣ End date: 14/01/2021

4. Suspect Medicines

Casirivimab+Imdevimab

‣ Drug Characterisation: Suspect
‣ Drug Dosage: 8 G gram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Intravenous infusion
‣ Route of Administration: Intravenous drip
‣ Indication: 2019-nCoV infection
‣ Start date: 14/01/2021
‣ End date: 14/01/2021
‣ Action Taken: Not applicable

PROPOFOL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 150 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Intravenous infusion
‣ Route of Administration: Intravenous drip
‣ Indication: Sedation
‣ Start date: 13/01/2021
‣ End date: 16/01/2021

5. Causality Assessment

Casirivimab+Imdevimab - Seizure

‣ Assessment by sponsor: Reasonable possibility
‣ Assessment by investigator: Reasonable possibility