

Report Overview - GB-MHRA-ESUSAR-215840423001-00110034

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 09/06/2021

1. Trial Information

- Reference: RECOVERY SUSAR 012
- Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

2. Patient Details

- Patient gender: Male
- Patient age at time of the side effect: 79 Years
- Patient Identification Number: 1175246

Chronic kidney disease stage 5

- Continuing: Yes

Hypothyroidism

- Continuing: Yes

Type II diabetes mellitus

- Continuing: Yes

Hypertension

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

23/11/2020

Country of Origin:

United Kingdom

Narrative:

79 year old man with diabetes, hypertension and requiring chronic haemodialysis admitted with COVID-19 on 14 November 2020 having developed symptoms on 9 November. He was randomised into RECOVERY on 17 November between convalescent plasma, REGN-COV2 and usual care (the other available treatments were unsuitable). He received REGN-COV2 on 17 November without immediate complication. On 20 November 202 he experienced a 45

minute period of reduced GCS (3/15), no observed seizure activity, stable observations. No tongue biting or faecal incontinence (patient was catheterised). Maintained own airway and did not require any intervention. Drowsy after episode, but able to answer questions and follow commands. CT head showed no acute event, normal ECG, blood sugars, other bloods unremarkable, and neurology review was inconclusive with regards to the nature of the event. Full recovery made. This event is reported late because although investigator did not confirm reasonable probability of relatedness the MHRA have instructed us to report this as a SUSAR.

Seriousness

- Other

Unconscious

- **Reaction Outcome:** Not Recovered
- **Start date:** 20/11/2020
- **End date:** 20/11/2020

Blood glucose

- **Result:** 15
- **Unit:** mmol/L
- **Test date:** 20/11/2020

Computerised tomogram head normal

- **Result:** Normal
- **Test date:** 20/11/2020

Electrocardiogram

- **Result:** Normal
- **Test date:** 20/11/2020

4. Suspect Medicines

Casirivimab+imdevimab

- **Drug Characterisation:** Suspect
- **Drug Dosage:** 8 G gram(s)
- **Drug Dosage Interval:** 1 Hours
- **Form:** Intravenous infusion
- **Route of Administration:** Intravenous (not otherwise specified)
- **Indication:** COVID-19
- **Start date:** 17/11/2020
- **End date:** 17/11/2020
- **Action Taken:** Dose not changed

5. Causality Assessment

Casirivimab+imdevimab - Unconscious

- **Assessment by sponsor:** No reasonable possibility
- **Assessment by investigator:** Reasonable possibility