

## 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