

Report Overview - GB-MHRA-ESUSAR-215840423001-00109842

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 19/05/2021

1. Trial Information

- Reference: RECOVERY SUSAR 009
- 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: 67 Years
- Patient Identification Number: 1335411

Diabetes mellitus

- Start date: 01/01/2015
- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
04/02/2021

Country of Origin:
United Kingdom

Narrative:

67 year old man admitted to hospital with COVID-19 on 27-Jan-2021. Provided informed consent for RECOVERY on 30-Jan-2021. On 30-Jan-2021 randomised and allocated REGN-COV2 (also assigned to usual care in both the colchicine and aspirin comparisons). Also admitted to intensive care, intubated and ventilated. REGN-COV2 infusion administered on 01-Feb-2021 without incident (completed at 15:51h). Sedation hold (propofol, morphine and midazolam) started once infusion completed and 1 hour later seizure activity noted: eyes rolling back in head, with sluggish pupils. Possible rhythmic movements of face, but no limb movements. Episode lasted 30 seconds and then spontaneously stopped; recurred 1 minute later (for a further 30 seconds) but again spontaneously stopped. Reviewing doctor was not concerned given that patient was waking from sedation. Event initially reported as serious and related, but local PI considered it to "no longer satisfy SUSAR reporting criteria" on discussion with RECOVERY clinicians. Reported as SUSAR on MHRA's instruction.

Seriousness

- Other

Seizure

▸ Reaction Outcome:	Recovered
▸ Start date:	01/02/2021
▸ End date:	01/02/2021

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:	01/02/2021
▸ End date:	01/02/2021
▸ Action Taken:	Not applicable

CARBOCISTEINE

▸ Drug Characterisation:	Concomitant
▸ Drug Dosage:	750 Mg milligram(s)
▸ Drug Dosage Interval:	8 Hours
▸ Form:	Powder and solvent for oral suspension
▸ Route of Administration:	Oral
▸ Indication:	COVID-19
▸ Start date:	31/01/2021
▸ Action Taken:	Not applicable

DEXAMETHASONE

▸ Drug Characterisation:	Concomitant
▸ Drug Dosage:	6 Mg milligram(s)
▸ Drug Dosage Interval:	1 Days
▸ Form:	Intravenous infusion
▸ Route of Administration:	Intravenous bolus
▸ Indication:	COVID-19
▸ Start date:	27/01/2021
▸ Action Taken:	Not applicable

ENOXAPARINE

▸ Drug Characterisation:	Concomitant
▸ Drug Dosage:	40 Mg milligram(s)
▸ Drug Dosage Interval:	12 Hours
▸ Form:	Injection
▸ Route of Administration:	Subcutaneous
▸ Indication:	COVID-19
▸ Start date:	27/01/2021
▸ Action Taken:	Not applicable

ESOMEPRAZOLE

▸ Drug Characterisation:	Concomitant
▸ Drug Dosage:	40 Mg milligram(s)
▸ Drug Dosage Interval:	1 Days
▸ Form:	Intravenous infusion
▸ Route of Administration:	Intravenous (not otherwise specified)

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|-----------------|---------------------------|
| ‣ Indication: | Gastric ulcer prophylaxis |
| ‣ Start date: | 31/01/2021 |
| ‣ Action Taken: | Not applicable |

FEXOFENADINE

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|----------------------------|---------------------|
| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 180 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 1 Days |
| ‣ Form: | Capsule |
| ‣ Route of Administration: | Oral |
| ‣ Indication: | Allergy |
| ‣ Start date: | 28/01/2021 |
| ‣ Action Taken: | Not applicable |

FUROSEMIDE

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|----------------------------|----------------------|
| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 20 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 8 Hours |
| ‣ Form: | Intravenous infusion |
| ‣ Route of Administration: | Intravenous bolus |
| ‣ Indication: | Diuretic therapy |
| ‣ Start date: | 01/02/2021 |
| ‣ Action Taken: | Not applicable |

HUMULIN I

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|----------------------------|-----------------------------|
| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 24 Iu international unit(s) |
| ‣ Drug Dosage Interval: | 12 Hours |
| ‣ Form: | Injection |
| ‣ Route of Administration: | Subcutaneous |
| ‣ Indication: | Diabetes mellitus |
| ‣ Start date: | 27/01/2021 |
| ‣ Action Taken: | Not applicable |

LINAGLIPTIN

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|----------------------------|-------------------|
| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 5 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 1 Days |
| ‣ Form: | Capsule |
| ‣ Route of Administration: | Oral |
| ‣ Indication: | Diabetes mellitus |
| ‣ Start date: | 27/01/2021 |
| ‣ Action Taken: | Not applicable |

NOREPINEPHRINE

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|----------------------------|---------------------------------------|
| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 20 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 60 Minutes |
| ‣ Form: | Intravenous infusion |
| ‣ Route of Administration: | Intravenous (not otherwise specified) |
| ‣ Indication: | Hypotension |
| ‣ Start date: | 30/01/2021 |
| ‣ Action Taken: | Not applicable |

PROPOFOL

- | | |
|--------------------------|-------------|
| ‣ Drug Characterisation: | Concomitant |
|--------------------------|-------------|

‣ Drug Dosage:	1 % percent
‣ Drug Dosage Interval:	60 Minutes
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous (not otherwise specified)
‣ Indication:	Monitored anaesthesia care sedation
‣ Start date:	31/01/2021
‣ Action Taken:	Not applicable

5. Causality Assessment

casirivimab+imdevimab - Seizure

‣ Assessment by sponsor:	No reasonable possibility
‣ Assessment by investigator:	Reasonable possibility