

Report Overview - GB-MHRA-ESUSAR-215840423001-00108254

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 27/01/2021

1. Trial Information

- Reference: RECOVERY SUSAR 005
- 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: 88 Years
- Patient Identification Number: 1315786

Atrial fibrillation

- Continuing: Yes

Congestive heart failure

- Continuing: Yes

Back pain

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

25/01/2021

Country of Origin:

United Kingdom

Narrative:

Participant recruited into trial on 25-Jan-2021 having been admitted with COVID-19 on 22-Jan-2021. Allocated REGN-COV2 and treatment began at 1700h that day. After receiving 2 mL of infusion she complained of being "unable to breathe" and looked flushed. Her respiratory rate was 40 breaths per minute, heart rate 115 bpm and saturations were 92% on air. She was treated for an allergic reaction with hydrocortisone, chlorpheniramine and oxygen was given. The infusion was stopped. 40 minutes later she became agitated and complained of shortness of breath. She also had back pain and was shivering. Medical review differential diagnosis included a rigor or pulmonary oedema. She was given IV furosemide. The episode resolved and she has recovered.

Seriousness

▸ Other

Acute allergic reaction

▸ Reaction Outcome: Not Recovered
▸ Start date: 25/01/2021
▸ End date: 25/01/2021

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: COVID-19
▸ Start date: 25/01/2021
▸ End date: 25/01/2021
▸ Action Taken: Drug withdrawn

FUROSEMIDE

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 60 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Coated tablet
▸ Route of Administration: Oral
▸ Indication: Cardiac failure congestive
▸ Start date: 01/01/2021
▸ Action Taken: Not applicable

BISOPROLOL

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 2.5 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Coated tablet
▸ Route of Administration: Oral
▸ Indication: Atrial fibrillation
▸ Start date: 01/01/2021
▸ Action Taken: Not applicable

APIXABAN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 2.5 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Coated tablet
▸ Route of Administration: Oral
▸ Indication: Atrial fibrillation
▸ Start date: 01/01/2021
▸ Action Taken: Not applicable

DEXAMETHASON

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 6 Mg milligram(s)

- ▶ **Drug Dosage Interval:** 1 Days
- ▶ **Form:** Coated tablet
- ▶ **Route of Administration:** Oral
- ▶ **Indication:** COVID-19
- ▶ **Start date:** 25/01/2021
- ▶ **Action Taken:** Not applicable

ASPIRIN COATED

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 150 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 1 Days
- ▶ **Form:** Coated tablet
- ▶ **Route of Administration:** Oral
- ▶ **Indication:** COVID-19
- ▶ **Start date:** 22/01/2021
- ▶ **Action Taken:** Not applicable

COLCHICINE

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 500 µg microgram(s)
- ▶ **Drug Dosage Interval:** 12 Hours
- ▶ **Form:** Coated tablet
- ▶ **Route of Administration:** Oral
- ▶ **Indication:** COVID-19
- ▶ **Start date:** 22/01/2021

5. Causality Assessment

Casirivimab+Imdevimab - Acute allergic reaction

- ▶ **Assessment by sponsor:** Reasonable possibility
- ▶ **Assessment by investigator:** Reasonable possibility