

Report Overview - GB-MHRA-ESUSAR-215840423001-00110033

Submission Details

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

1. Trial Information

- Reference: RECOVERY SUSAR 011
▸ 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: 62 Years
▸ Patient Identification Number: 1300120

Obesity

- Continuing: Yes

Type II diabetes mellitus without mention of complication

- Continuing: Yes

Ischaemic heart disease

- Continuing: Yes

Hypertension

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

20/01/2021

Country of Origin:

United Kingdom

Narrative:

62 year old man admitted to hospital on 20 January 2020 having developed symptoms of COVID-19 on 24 December 2020. Was hypoxic and required CPAP therapy. Provided informed consent for RECOVERY and randomised between REGN-COV2 and usual care (other available arms not suitable). Infusion of REGN-COV2 started at 15:16h and nurses reported that shortly after starting infusion participant became flushed, hypotensive and tachycardic.

Infusion stopped and participant recovered spontaneously without intervention. Site rated severity as 'mild'. Reported late because although site revised seriousness decision (to non-serious), MHRA have instructed sponsor to report as a SUSAR.

Seriousness

- Other

Infusion reaction

- Reaction Outcome: Recovered with sequelae
- Start date: 20/01/2021
- End date: 20/01/2021

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: 20/01/2021
- End date: 20/01/2021
- Action Taken: Drug withdrawn

OMEPRAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 40 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Gastric ulcer prophylaxis
- Start date: 20/01/2021
- Action Taken: Not applicable

ENOXAPARIN

- Drug Characterisation: Concomitant
- Drug Dosage: 60 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Solution for injection
- Route of Administration: Subcutaneous
- Indication: Venous thromboembolism prophylaxis
- Start date: 20/01/2021
- Action Taken: Not applicable

DEXAMETHASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 6 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 20/01/2021
- Action Taken: Not applicable

AMLODIPINE

- Drug Characterisation: Concomitant
- Drug Dosage: 5 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Hypertension
- Start date: 20/01/2021
- Action Taken: Not applicable

VENLAFAXINE

- Drug Characterisation: Concomitant
- Drug Dosage: 150 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Chronic depression
- Start date: 20/01/2021
- Action Taken: Not applicable

NICORANDIL

- Drug Characterisation: Concomitant
- Drug Dosage: 10 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral
- Indication: Angina pectoris
- Start date: 20/01/2021
- Action Taken: Not applicable

ATORVASTATIN

- Drug Characterisation: Concomitant
- Drug Dosage: 40 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Ischaemic heart disease
- Start date: 20/01/2021
- Action Taken: Not applicable

AMOXICILLIN

- Drug Characterisation: Concomitant
- Drug Dosage: 1 G gram(s)
- Drug Dosage Interval: 8 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Pneumonia
- Start date: 20/01/2021
- Action Taken: Not applicable

DOXYCYCLINE

- Drug Characterisation: Concomitant
- Drug Dosage: 200 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Form: Tablet
- Route of Administration: Oral

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| ‣ Indication: | Pneumonia |
| ‣ Start date: | 20/01/2021 |
| ‣ Action Taken: | Not applicable |

ASPIRIN

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| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 75 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 1 Days |
| ‣ Form: | Tablet |
| ‣ Route of Administration: | Oral |
| ‣ Indication: | Ischaemic heart disease |
| ‣ Start date: | 20/01/2021 |
| ‣ Action Taken: | Not applicable |

5. Causality Assessment

Casirivimab+imdevimab - Infusion reaction

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