

Report Overview - GB-MHRA-ESUSAR-215840423001-00110300

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 05/07/2021

1. Trial Information

- Reference: RECOVERY SUSAR 013
- 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: 74 Years
- Patient Identification Number: 1401623

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
02/07/2021

Country of Origin:
United Kingdom

Narrative:

No prior medical history; had not seen doctor in >40 years. Admitted on 19-Jun-2021 with productive cough and fever (symptoms began on 14-Jun-2021). COVID PCR test was positive. Had not been vaccinated against SARS-CoV-2. Started on dexamethasone, remdesivir and tocilizumab. Oxygenation required CPAP support. Provided consent and was randomised into RECOVERY on 22-Jun-2021 and was allocated baricitinib. On 01-Jul-2021 developed abdominal pain and CT scan showed evidence of perforated viscus so taken to theatre for laparotomy. Pre-existing sigmoid diverticular disease found with evidence of perforation. Hartmann's procedure performed. Now recovering on ICU.

Seriousness

- Life threatening

Diverticular perforation

- Reaction Outcome: Recovering
- Start date: 01/07/2021

Computerised axial tomography abnormal

- Result: Air in peritoneal cavity

▸ Test date: 01/07/2021

4. Suspect Medicines

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: 19/06/2021
▸ End date: 29/06/2021
▸ Action Taken: Not applicable

REMDESIVIR

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 100 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Intravenous infusion
▸ Route of Administration: Intravenous (not otherwise specified)
▸ Indication: COVID-19
▸ Start date: 19/06/2021
▸ End date: 23/06/2021
▸ Action Taken: Not applicable

TOCILIZUMAB

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 800 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Intravenous infusion
▸ Route of Administration: Intravenous (not otherwise specified)
▸ Indication: COVID-19
▸ Start date: 23/06/2021
▸ End date: 23/06/2021
▸ Action Taken: Not applicable

BARICITINIB

▸ Drug Characterisation: Suspect
▸ Drug Dosage: 4 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Indication: COVID-19
▸ Start date: 22/06/2021
▸ End date: 01/07/2021
▸ Action Taken: Drug withdrawn

MELATONIN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 6 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Indication: Poor sleep

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| ‣ Start date: | 23/06/2021 |
| ‣ Action Taken: | Not applicable |

CO-AMOXICLAV

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| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 1.2 G gram(s) |
| ‣ Drug Dosage Interval: | 8 Hours |
| ‣ Form: | Intravenous infusion |
| ‣ Route of Administration: | Intravenous bolus |
| ‣ Indication: | Acute pneumonia |
| ‣ Start date: | 19/07/2021 |
| ‣ End date: | 24/07/2021 |
| ‣ Action Taken: | Not applicable |

ENOXAPARIN

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| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 40 Mg milligram(s) |
| ‣ Drug Dosage Interval: | 1 Days |
| ‣ Form: | Suspension for injection in pre-filled syringe |
| ‣ Route of Administration: | Subcutaneous |
| ‣ Indication: | Venous thromboembolism prophylaxis |
| ‣ Start date: | 19/06/2021 |
| ‣ Action Taken: | Not applicable |

INSULIN

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| ‣ Drug Characterisation: | Concomitant |
| ‣ Drug Dosage: | 8 lu international unit(s) |
| ‣ Drug Dosage Interval: | 8 Hours |
| ‣ Form: | Solution for injection in pre-filled syringe |
| ‣ Route of Administration: | Subcutaneous |
| ‣ Indication: | Diabetes mellitus |
| ‣ Start date: | 19/06/2021 |
| ‣ Action Taken: | Not applicable |

5. Causality Assessment

BARICITINIB - Diverticular perforation

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