

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

- ▶ Start date: 23/06/2021
- ▶ Action Taken: Not applicable

CO-AMOXICLAV

- ▶ 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

- ▶ 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

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 8 Iu 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

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