

Report Overview - GB-MHRA-ESUSAR-215840423001-00110499

Submission Details

- Submitted by: Prof Richard Haynes
Submission date: 27/07/2021

1. Trial Information

- Reference: RECOVERY SUSAR 014
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: 1406707

Hypertension

- Continuing: Yes

Type 2 diabetes mellitus

- Start date: 2016
Continuing: Yes

Recurrent UTI

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
21/07/2021

Country of Origin:
United Kingdom

Narrative:

Patient presented to hospital with severe covid pneumonia, and Covid-19 and treatment commenced as standard of care for Covid-19 on 12/07/2021 (after positive lateral flow test and PCR), dexamethasone commenced as standard of care. On 13/07/2021, Remdesivir commenced with consent, and Tocilizumab once off dose given. Recruited to Recovery trial on 14/07/2021 after eligibility assessment from medical and pharmacy team and informed consent given by participant. Randomised to Baricitinib full dose 4mg OD commenced 14/07/2021. Had 5 doses of Baricitinib. On 20/07/2021 had medical review after bowels not opened for 3 days and abdominal discomfort and sent for CT abdomen, with CT report of small bowel perforation with report of diverticulitis, and baricitinib stopped.IV

antibiotics given as per microguide and NBM. Had emergency laparotomy on 20/07/2021 and transferred to ITU where patient is currently stable.

Seriousness

- Life threatening

Small intestinal perforation

- Reaction Outcome: Recovering
- Start date: 20/07/2021

Computerised tomogram abdomen abnormal

- Result: bowel perforation, most likely of the small bowel
- Test date: 20/07/2021

4. Suspect Medicines

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: 14/07/2021
- End date: 19/07/2021
- Action Taken: Drug withdrawn

CO-AMOXICLAV

- Drug Characterisation: Concomitant
- Drug Dosage: 1.2 G gram(s)
- Drug Dosage Interval: 8 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Abdominal sepsis
- Start date: 20/07/2021
- Action Taken: Not applicable

GENTAMICIN

- Drug Characterisation: Concomitant
- Drug Dosage: 240 Mg milligram(s)
- Drug Dosage Interval: 1
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Laparotomy
- Action Taken: Not applicable

METRONIDAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 500 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Bowel perforation
- Start date: 20/07/2021

‣ Action Taken: Not applicable

PARACETAMOL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 1 G gram(s)
‣ Drug Dosage Interval: 6 Hours
‣ Form: Intravenous infusion
‣ Route of Administration: Intravenous (not otherwise specified)
‣ Start date: 20/07/2021
‣ Action Taken: Not applicable

5. Causality Assessment

BARICITINIB - Small intestinal perforation

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