

Report Overview - GB-MHRA-ESUSAR-215840423001-00108622

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 20/02/2021

1. Trial Information

- Reference: RECOVERY SUSAR 007
- 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: 81 Years
- Patient Identification Number: 1351252

Transient ischaemic attack

- Continuing: No

Hypertension

- Continuing: Yes

Diverticular disease

- Continuing: Yes

Anxiety

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

18/02/2021

Country of Origin:

United Kingdom

Narrative:

Admitted to hospital on 5-Feb-21 with severe COVID requiring CPAP. Dexamethasone started on admission. On 6-Feb-21 recruited to RECOVERY and randomised to receive baricitinib. C-reactive protein initially fell (286 mg/L on admission to 26 mg/L on 9-Feb-21) but then later rose (151 on 17-Feb-21) with abdominal pain. CT scan showed pneumoperitoneum with sigmoid perforation, most likely at time of randomisation. Treated conservatively with

intravenous antibiotics.

Seriousness

- Hospitalisation

Acute diverticular perforation

- Reaction Outcome: Recovering
- Start date: 17/02/2021

Abdomen CT

- Result: Acute diverticular perforation
- Test date: 17/02/2021

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: 06/02/2021
- End date: 15/02/2021
- Action Taken: Drug withdrawn

MIRTAZAPIN

- Drug Characterisation: Concomitant
- Drug Dosage: 15 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Anxiety
- Start date: 05/02/2021
- Action Taken: Not applicable

CLOPIDOGREL SULPHATE

- Drug Characterisation: Concomitant
- Drug Dosage: 75 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Transient ischaemic attack
- Start date: 05/02/2021
- Action Taken: Not applicable

ATORVASTATIN CALCIUM

- Drug Characterisation: Concomitant
- Drug Dosage: 20 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: Transient ischaemic attack
- Start date: 05/02/2021

‣ Action Taken: Not applicable

AMLODIPIN

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 5 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Hypertension
‣ Start date: 05/02/2021
‣ 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: 05/02/2021
‣ Action Taken: Not applicable

ATENOLOL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 50 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Hypertension
‣ Start date: 05/02/2021
‣ Action Taken: Not applicable

RAMIPRIL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 5 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Hypertension
‣ Start date: 05/02/2021
‣ Action Taken: Not applicable

OMEPRAZOL

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 20 Mg milligram(s)
‣ Drug Dosage Interval: 1 Days
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Prophylaxis against gastrointestinal ulcer
‣ Start date: 05/02/2021

▸ Action Taken: Not applicable

5. Causality Assessment

BARICITINIB - Acute diverticular perforation

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