

Report Overview - VN-MHRA-ESUSAR-215840423001-00111202

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 05/10/2021

1. Trial Information

- Trial Name: 2020-001113-21 RECOVERY - Randomised Evaluation of COVID-19 Therapy

2. Patient Details

- Patient gender: Female
- Patient age at time of the side effect: 35 Years
- Patient Identification Number: 1433919

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
04/10/2021

Country of Origin:
Vietnam

Narrative:

35 year old female developed symptoms of COVID-19 on 17-Sep-2021 and admitted to hospital on 27-Sep-2021. Required transfer to ICU and intubated and ventilated. Randomised into RECOVERY on 27-Sep-2021 and allocated high-dose dexamethasone. Also treated with treatment-dose heparin. Shortly after first dose of dexamethasone, gastric aspirate was suspicious for gastrointestinal bleeding. Study treatment stopped. CT pulmonary angiogram (done to investigate for pulmonary embolism) showed pneumomediastinum and free air in peritoneum. Suspected bowel perforation so transferred to another hospital for further management.

Seriousness

- Life threatening

Perforated bowel

- Reaction Outcome: Recovered with sequelae
- Start date: 30/09/2021

Gastrointestinal bleed

- Reaction Outcome: Unknown
- Start date: 27/09/2021

CT pulmonary angiogram

- ▶ **Result:** Pneumomediastinum and free air in peritoneum
- ▶ **Test date:** 30/09/2021

4. Suspect Medicines

DEXAMETHASONE

- ▶ **Drug Characterisation:** Suspect
- ▶ **Drug Dosage:** 20 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 1 Days
- ▶ **Form:** Intravenous infusion
- ▶ **Route of Administration:** Intravenous bolus
- ▶ **Indication:** COVID-19
- ▶ **Start date:** 27/09/2021
- ▶ **End date:** 30/09/2021
- ▶ **Action Taken:** Drug withdrawn

ENOXAPARIN

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 80 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 12 Hours
- ▶ **Form:** Solution for injection in pre-filled syringe
- ▶ **Route of Administration:** Subcutaneous
- ▶ **Indication:** COVID-19
- ▶ **Start date:** 27/09/2021
- ▶ **End date:** 27/09/2021
- ▶ **Action Taken:** Drug withdrawn

ESOMEPRAZOLE

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** 80 Mg milligram(s)
- ▶ **Drug Dosage Interval:** 1 Days
- ▶ **Form:** Intravenous infusion
- ▶ **Route of Administration:** Intravenous drip
- ▶ **Indication:** Gastrointestinal bleeding
- ▶ **Start date:** 27/09/2021
- ▶ **Action Taken:** Not applicable

PIPERACILLIN and TAZOBACTAM

- ▶ **Drug Characterisation:** Concomitant
- ▶ **Drug Dosage:** G gram(s)
- ▶ **Drug Dosage Interval:** 8 Hours
- ▶ **Form:** Intravenous infusion
- ▶ **Route of Administration:** Intravenous bolus
- ▶ **Indication:** Bacterial infection
- ▶ **Start date:** 27/09/2021
- ▶ **Action Taken:** Not applicable

5. Causality Assessment

DEXAMETHASONE - Perforated bowel

- Assessment by sponsor: Reasonable possibility
 - Assessment by investigator: Reasonable possibility
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DEXAMETHASONE - Gastrointestinal bleed

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