

Report Overview - VN-MHRA-ESUSAR-215840423001-00111214

Submission Details

- Submitted by: Prof Richard Haynes
▸ Submission date: 04/11/2021

1. Trial Information

- Reference: SUSAR 019 follow-up
▸ 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: 72 Years
▸ Patient Identification Number: 1434782

Hypertension

- Continuing: Yes

Diabetes mellitus NOS

- Continuing: Yes

Ischaemic stroke NOS

- Continuing: No

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

06/10/2021

Country of Origin:

Vietnam

Narrative:

72-year-old female with hypertension, diabetes, ischemic stroke, no history of stomach ulcers. On 29/09/21, she was transferred from a district hospital for covid-19 disease with acute respiratory failure requiring invasive mechanical ventilation on admission. Abdomen soft and bloated on admission. Nasogastric tube inserted, antibiotics, dexamethasone 10mg and PPI given. Randomised in RECOVERY on 29/09/21 and received high-dose dexamethasone treatment allocation (total 20mg per day). CT scan on 01/10/21 showed pneumothorax, pneumomediastinum and pneumoperitoneum. Treating clinician suspected gastrointestinal perforation and stopped study high-dose dexamethasone On 12/10/21, 29/10/21 and 02/11/21 further follow-up information received; decreasing of pneumothorax, pneumomediastinum, pneumoperitoneum was observed. Soft and non-tender abdomen.

Dexamethasone was not restarted. Patient did not have confirmation of a perforated viscus. No surgery was performed. From 30/09/21 to 10/10/21 had fever with persistent multi-organ failure. Treated empirically with broad-spectrum antibiotics and later empirical anti-fungals added. No positive microbiology. Most likely source bacterial pneumonia. Continued to deteriorate with refractory septic shock and died on 10/10/21. On 29/10/21 it was confirmed that the local investigator still felt there was a possibility of the reported pneumoperitoneum event being related to dexamethasone study treatment

Seriousness

- Other

Pneumoperitoneum

- Reaction Outcome: Unknown
- Start date: 01/10/2021

Pneumonia bacterial

- Reaction Outcome: Fatal
- Start date: 09/10/2021

Computerized tomography abnormal

- Result: Pneumothorax, pneumomediastinum, pneumoperitoneum
- Test date: 01/10/2021

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 (not otherwise specified)
- Indication: COVID-19
- Start date: 29/09/2021
- End date: 01/10/2021
- Action Taken: Drug withdrawn

IMIPENEM

- Drug Characterisation: Concomitant
- Drug Dosage: 2 G gram(s)
- Drug Dosage Interval: 12 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Pneumonia
- Start date: 29/09/2021
- Action Taken: Not applicable

VANCOMYCIN

- Drug Characterisation: Concomitant
- Drug Dosage: 1 G gram(s)
- Drug Dosage Interval: 12 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous (not otherwise specified)
- Indication: Pneumonia
- Start date: 30/09/2021
- Action Taken: Not applicable

ESOMEPRAZOLE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	80 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous (not otherwise specified)
‣ Indication:	Gastrointestinal perforation
‣ Start date:	01/10/2021
‣ Action Taken:	Not applicable

ENOXAPARIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	40 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Injection
‣ Route of Administration:	Subcutaneous
‣ Indication:	Venous thromboembolism prophylaxis
‣ Start date:	29/09/2021
‣ Action Taken:	Not applicable

NICARDIPINE

‣ Drug Characterisation:	Concomitant
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous (not otherwise specified)
‣ Indication:	Hypertension NOS
‣ Start date:	01/10/2021
‣ Action Taken:	Not applicable

ALBUMIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	40 G gram(s)
‣ Drug Dosage Interval:	6 Hours
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous (not otherwise specified)
‣ Indication:	Albumin low
‣ Start date:	30/09/2021
‣ Action Taken:	Not applicable

BISOPROLOL

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	5 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Hypertension
‣ Start date:	30/09/2021
‣ Action Taken:	Not applicable

VITAMIN B CONCENTRATES

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage Interval:	1 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Nutritional supplementation
‣ Start date:	30/09/2021

‣ Action Taken: Not applicable

ACETYLCYSTEIN

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 600 Mg milligram(s)
‣ Drug Dosage Interval: 8 Hours
‣ Form: Tablet
‣ Route of Administration: Oral
‣ Indication: Pneumonia
‣ Start date: 30/09/2021
‣ Action Taken: Not applicable

DUPHALAC

‣ Drug Characterisation: Concomitant
‣ Drug Dosage: 40 G gram(s)
‣ Drug Dosage Interval: 12 Hours
‣ Form: Oral solution
‣ Route of Administration: Oral
‣ Indication: Constipation
‣ Start date: 01/10/2021
‣ Action Taken: Not applicable

5. Causality Assessment

Dexamethasone - Pneumoperitoneum

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

Dexamethasone - Pneumonia bacterial

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