

Report Overview - GB-MHRA-ESUSAR-215840423001-00110755

Submission Details

- ▶ Submitted by: Prof Richard Haynes
▶ Submission date: 23/08/2021

1. Trial Information

- ▶ Reference: RECOVERY SUSAR 016
▶ 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: 60 Years
▶ Patient Identification Number: 1421003

Diabetes steroid-induced

- ▶ Continuing: Yes

Bronchiectasis

- ▶ Continuing: Yes

Asthma

- ▶ Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

20/08/2021

Country of Origin:

United Kingdom

Narrative:

Patient with steroid-induced diabetes mellitus usually on gliclazide. Hospitalised with severe COVID-19 requiring NIV. Randomised to empagliflozin and commenced treatment on 18/08/21. Gliclazide stopped on 18/08/21 due to hypoglycaemia. 19/08/21: Received empagliflozin. Poor nutritional intake. Blood ketones raised on check (2.6), no acidosis, empagliflozin stopped. Other causes of ketosis excluded. 20/08/21 Ketones still raised at 2.9, enteral nutrition started and commenced on variable rate insulin infusion on endocrinology team advice with resolution of ketosis a few hours later. Development of ketosis felt to be a serious event as required insulin infusion for correction. 21/08/21 Patient declined NIV and died from respiratory failure relating to underlying COVID, death not felt to be related to ketosis by local investigator and responsible clinical team.

Seriousness

▸ Other

Diabetic ketosis

▸ Reaction Outcome: Recovering
▸ Start date: 20/08/2021

Blood ketone body increased

▸ Result: 2.9
▸ Unit: mmol/L
▸ Test date: 20/08/2021

4. Suspect Medicines**EMPAGLIFLOZIN**

▸ Drug Characterisation: Suspect
▸ Drug Dosage: 10 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Indication: COVID-19
▸ Start date: 18/08/2021
▸ End date: 20/08/2021
▸ Action Taken: Drug withdrawn

INSULIN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage Interval: 0 Minutes
▸ Form: Infusion
▸ Route of Administration: Intravenous (not otherwise specified)
▸ Indication: Diabetic ketosis
▸ Start date: 20/08/2021
▸ Action Taken: Not applicable

MONTELUKAST

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 10 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Action Taken: Not applicable

ASPIRIN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 75 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Route of Administration: Oral
▸ Action Taken: Not applicable

FEXOFENADINE

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 180 Mg milligram(s)

- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

HIZENTRA

- Drug Characterisation: Concomitant
- Drug Dosage: 9 G gram(s)
- Drug Dosage Interval: 1 Weeks
- Route of Administration: Subcutaneous
- Action Taken: Not applicable

CARBOCISTEINE

- Drug Characterisation: Concomitant
- Drug Dosage: 750 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

GLICLAZIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 80 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Indication: Diabetes steroid-induced
- End date: 18/08/2021
- Action Taken: Not applicable

DUORESP SPIROMAX

- Drug Characterisation: Concomitant
- Drug Dosage Interval: 12 Hours
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

IVABRADINE

- Drug Characterisation: Concomitant
- Drug Dosage: 5 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

ATORVASTATIN

- Drug Characterisation: Concomitant
- Drug Dosage: 40 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

SALBUTAMOL

- Drug Characterisation: Concomitant
 - Drug Dosage: 2.5 Mg milligram(s)
 - Drug Dosage Interval: 6 Hours
 - Form: Nebuliser solution
 - Route of Administration: Respiratory (inhalation)
 - Action Taken: Not applicable
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IPRATROPIUM

- Drug Characterisation: Concomitant
- Drug Dosage: 500 µg microgram(s)
- Drug Dosage Interval: 6 Hours
- Form: Nebuliser solution
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

FLUTICASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 27.5 µg microgram(s)
- Route of Administration: Respiratory (inhalation)
- Action Taken: Not applicable

TICAGRELOR

- Drug Characterisation: Concomitant
- Drug Dosage: 90 Mg milligram(s)
- Drug Dosage Interval: 12 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

LANSOPRAZOLE

- Drug Characterisation: Concomitant
- Drug Dosage: 30 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

CARBOMER

- Drug Characterisation: Concomitant
- Form: Eye drops
- Route of Administration: Topical
- Action Taken: Not applicable

SODIUM HYALURONATE

- Drug Characterisation: Concomitant
- Drug Dosage: 0.1 % percent
- Drug Dosage Interval: 12 Hours
- Form: Eye drops
- Route of Administration: Topical
- Action Taken: Not applicable

DEXAMETHASONE

- Drug Characterisation: Concomitant
- Drug Dosage: 6 Mg milligram(s)
- Drug Dosage Interval: 1 Days
- Route of Administration: Oral
- Action Taken: Not applicable

CYCLIZINE

- Drug Characterisation: Concomitant
- Drug Dosage: 50 Mg milligram(s)
- Drug Dosage Interval: 8 Hours
- Route of Administration: Oral
- Action Taken: Not applicable

COLISTIMETHATE

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 2 Miu iu(1,000,000s)
- ▶ Drug Dosage Interval: 12 Hours
- ▶ Form: Nebuliser solution
- ▶ Route of Administration: Respiratory (inhalation)
- ▶ Action Taken: Not applicable

TAZOCIN

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 4.5 G gram(s)
- ▶ Drug Dosage Interval: 8 Hours
- ▶ Route of Administration: Intravenous (not otherwise specified)
- ▶ Action Taken: Not applicable

METOCLOPRAMIDE

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 10 Mg milligram(s)
- ▶ Drug Dosage Interval: 8 Hours
- ▶ Route of Administration: Oral
- ▶ Action Taken: Not applicable

ADCAL-D3

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 1 DF dosage form
- ▶ Drug Dosage Interval: 12 Hours
- ▶ Route of Administration: Oral
- ▶ Action Taken: Not applicable

SODIUM CHLORIDE

- ▶ Drug Characterisation: Concomitant
- ▶ Drug Dosage: 0.9 % percent
- ▶ Drug Dosage Interval: 6 Hours
- ▶ Form: Nebuliser solution
- ▶ Route of Administration: Respiratory (inhalation)
- ▶ Action Taken: Not applicable

5. Causality Assessment

EMPAGLIFLOZIN - Diabetic ketosis

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