

Report Overview - GB-MHRA-ESUSAR-215840423001-00111369

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 18/10/2021

1. Trial Information

- Reference: SUSAR 020
- 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: 49 Years
- Patient Identification Number: 1432122

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
15/10/2021

Country of Origin:
United Kingdom

Narrative:

Admitted to hospital with COVID-19 on 20th September 2021, treated with dexamethasone 6mg OD for 10 days. Randomised to empagliflozin within RECOVERY trial on the same day. The patient was not a known diabetic prior to randomisation. On 11th October 2021 found to have ketosis (blood ketone level 3.6 mmol/L), hyperglycaemia (blood glucose level 17.2mmol/L) and hyperosmolality (calculated osmolality 343mOsm/kg). Not acidotic: pH was within normal range at 7.42 and bicarbonate 16mmol/L. The empagliflozin was stopped and was commenced on treatment with IV fluids in accordance with Endocrinology team advice. Biochemical abnormalities resolving with treatment. Local investigator attributes the ketosis to empagliflozin but not the hyperglycaemic hyperosmolar state.

Seriousness

- Other

Ketosis

- Reaction Outcome: Recovering
- Start date: 11/10/2021

Diabetes with hyperosmolality

- Reaction Outcome: Recovering

▸ Start date: 11/10/2021

Blood ketone body increased

▸ Result: 3.6
▸ Unit: mmol/L
▸ Test date: 11/10/2021

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: 20/09/2021
▸ End date: 11/10/2021
▸ Action Taken: Drug withdrawn

FLUCLOXACILLIN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 2 G gram(s)
▸ Drug Dosage Interval: 6 Hours
▸ Form: Intravenous infusion
▸ Route of Administration: Intravenous (not otherwise specified)
▸ Start date: 04/10/2021
▸ Action Taken: Not applicable

DALTEPARIN

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 18000
▸ Drug Dosage Interval: 1 Days
▸ Form: Injection
▸ Route of Administration: Subcutaneous
▸ Indication: Pulmonary embolism
▸ Start date: 05/10/2021
▸ Action Taken: Not applicable

PARACETAMOL

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 1 G gram(s)
▸ Drug Dosage Interval: 6 Hours
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Start date: 05/10/2021
▸ Action Taken: Not applicable

MORPHINE

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 10 Mg milligram(s)
▸ Form: Oral solution
▸ Route of Administration: Oral
▸ Indication: Pain

- Start date: 08/10/2021
- Action Taken: Not applicable

SODIUM CHLORIDE

- Drug Characterisation: Concomitant
- Drug Dosage: 500 ml millilitre(s)
- Drug Dosage Interval: 2 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous drip
- Indication: Hyperosmolar hyperglycaemic state
- Start date: 11/10/2021
- End date: 12/10/2021
- Action Taken: Not applicable

GLUCOSE INTRAVENOUS INFUSION

- Drug Characterisation: Concomitant
- Drug Dosage: 500 ml millilitre(s)
- Drug Dosage Interval: 2 Hours
- Form: Intravenous infusion
- Route of Administration: Intravenous drip
- Indication: Hyperosmolar hyperglycaemic state
- Start date: 12/10/2021
- 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: 20/09/2021
- End date: 30/09/2021
- Action Taken: Not applicable

5. Causality Assessment

EMPAGLIFLOZIN - Ketosis

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

EMPAGLIFLOZIN - Diabetes with hyperosmolarity

- Assessment by sponsor: No reasonable possibility
- Assessment by investigator: No reasonable possibility