

Report Overview - GB-MHRA-ESUSAR-215840423001-00106393

Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 01/05/2020

1. Trial Information

- Reference: RECOVERY SUSAR 001
- 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: 83 Years
- Patient Identification Number: 1062919

Type 2 diabetes mellitus

- Continuing: Yes

Hypertension

- Continuing: Yes

Stroke

- Continuing: No

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:

29/04/2020

Country of Origin:

United Kingdom

Narrative:

Prolonged ICU stay for COVID pneumonia from 14/4. On sedation hold as had weaned to continuous positive airway pressure/pressure support ventilation - not tracheostomised - still with endotracheal tube. No vasopressors. Renal impairment on peritoneal dialysis acutely. Not awakening and CT head performed last 24 hours 29/4 1100) - nil of concern. Sudden short episode of spontaneous torsades de pointes/ventricular tachycardia with self resolution 28/4 0800. Not haemodynamically disturbed. HCQ stopped and cardiology referral made. QTC normal afterwards. Mg topped up although already more than 1 (1.54). Cardiology advised lignocaine if recurs and to avoid amiodarone as risk of QTC prolongation

Seriousness

▸ Other

Torsades de pointes

▸ Reaction Outcome: Recovered
▸ Start date: 28/04/2020
▸ End date: 28/04/2020

Blood potassium

▸ Result: 6.0
▸ Unit: mmol/L
▸ Test date: 28/04/2020

Blood magnesium

▸ Result: 1.5
▸ Unit: mmol/L
▸ Test date: 28/04/2020

Electrocardiogram

▸ Result: QTc 452
▸ Unit: milliseconds
▸ Test date: 28/04/2020

Electrocardiogram

▸ Result: QTc 435
▸ Unit: milliseconds
▸ Test date: 22/04/2020

4. Suspect Medicines**AMLODIPINE**

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 10 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Indication: Hypertension
▸ Start date: 01/01/2020
▸ Action Taken: Dose not changed

BISOPROLOL FUMARATE

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 5 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days
▸ Form: Tablet
▸ Route of Administration: Oral
▸ Indication: Hypertension
▸ Start date: 01/01/2020
▸ Action Taken: Dose not changed

CARBOCYSTEINE

▸ Drug Characterisation: Concomitant
▸ Drug Dosage: 750 Mg milligram(s)
▸ Drug Dosage Interval: 1 Days

‣ Form:	Syrup
‣ Route of Administration:	Oral
‣ Indication:	Acute pneumonia
‣ Start date:	14/04/2020
‣ Action Taken:	Dose not changed

ATORVASTATIN CALCIUM

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	40 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Hypercholesterolaemia
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ Action Taken:	Not applicable

CANDESARTAN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	32 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Hypertension
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ 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:	Stroke
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ Action Taken:	Not applicable

GLICLAZIDE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	160 Mg milligram(s)
‣ Drug Dosage Interval:	2 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Type II diabetes mellitus
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ Action Taken:	Not applicable

METFORMIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	1 G gram(s)
‣ Drug Dosage Interval:	2 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral

‣ Indication:	Type II diabetes mellitus
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ 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:	Acid reflux (esophageal)
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ Action Taken:	Not applicable

SITAGLIPTIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	100 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Tablet
‣ Indication:	Type II diabetes mellitus
‣ Start date:	01/01/2020
‣ End date:	14/04/2020
‣ Action Taken:	Not applicable

HEPARIN

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	5000
‣ Drug Dosage Interval:	1 Days
‣ Form:	Injection
‣ Route of Administration:	Subcutaneous
‣ Indication:	thromboprophylaxis
‣ Start date:	14/04/2020
‣ End date:	28/04/2020
‣ Action Taken:	Dose not changed

HYDROXYCHLOROQUINE

‣ Drug Characterisation:	Suspect
‣ Drug Dosage:	200 Mg milligram(s)
‣ Drug Dosage Interval:	2 Days
‣ Form:	Tablet
‣ Route of Administration:	Oral
‣ Indication:	Viral pneumonia
‣ Start date:	22/04/2020
‣ End date:	28/04/2020

▸ Action Taken:

Drug withdrawn

5. Causality Assessment

HYDROXYCHLOROQUINE - Torsades de pointes

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