

Report Overview - GB-MHRA-ESUSAR-215840426001-00110856

Submission Details

Submitted by: Prof Gail Hayward
Submission date: 02/09/2021

1. Trial Information

Trial Name: 2020-001209-22 PRINCIPLE - Platform Randomised trial of Interventions against COVID-19 In older peoPLE

2. Patient Details

Patient initials: GAA46810
Patient gender: Female
Patient age at time of the side effect: 76 Years
Patient Identification Number: GAA46810
Patient weight (kg): 76

Hypertension

Continuing: Unknown

BISOPROLOL FUMARATE

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
28/08/2021

Country of Origin:
United Kingdom

Narrative:

Participant was taking bisoprolol which was stopped before joining the trial. On the 20th/Aug/2021 tachycardia was noticed when participant went to health care for routine bloods. Participant started feeling unwell on the 26th/Aug/2021 and was admitted to the hospital. On the 28th/Aug/2021, bisoprolol was resumed and participant started feeling better with heart rate within normal range. Trial medication was taken 18th-20th August 2021.

Seriousness

Hospitalisation

Tachycardia

Reaction Outcome: Recovered

- Start date: 26/08/2021
- End date: 28/08/2021

Tachycardia

- Result: not known

4. Suspect Medicines

IVERMECTIN

- Drug Characterisation: Suspect
- Drug Dosage: 24 Mg milligram(s)
- Drug Dosage Interval: 3 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 18/08/2021
- End date: 20/08/2021
- Action Taken: Not applicable

5. Causality Assessment

IVERMECTIN - Tachycardia

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