

Report Overview - GB-MHRA-ESUSAR-215840426001-00113469

Submission Details

- Submitted by: Prof Gail Hayward
- Submission date: 12/05/2022

1. Trial Information

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

2. Patient Details

- Patient gender: Male
- Patient age at time of the side effect:
- Patient Identification Number: NHS57995

Benign essential hypertension

- Continuing: Yes

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
12/05/2022

Country of Origin:
United Kingdom

Narrative:

Acute Allergic Reaction. Pt called the safety line on 10th/May/2022 at 14:41. Pt took IMP today at 11:00 and pt started developing Itching in the genital area currently. No rash. No angioedema. No shortness of breath. Suggestion to take antihistamines and get in touch with GP. Pt called safety line on 10th/May/2022 at 15:38 reporting not being able to get in touch with GP. Pt has not taken antihistamines. The blood pressure readings are not displayed in the blood pressure machine meaning that currently the blood pressure is very high. Suggestion to hang up and call 999. Pt called safety line on 10th/May/2022 at 22:00 to update. Ambulance came within 10 minutes and on the way to the hospital pt developed a rash. Heart rate was 110. Pt was given intravenous antihistamines and now recovering. First episode in their lives. No known allergic conditions."

Seriousness

- Hospitalisation

Acute allergic reaction

- Reaction Outcome: Recovering
- Start date: 10/05/2022

4. Suspect Medicines

Favipiravir

▸ Drug Characterisation:	Suspect
▸ Drug Dosage:	2 G gram(s)
▸ Drug Dosage Interval:	1 Days
▸ Form:	Tablet
▸ Route of Administration:	Oral
▸ Indication:	COVID-19
▸ Start date:	10/05/2022
▸ End date:	10/05/2022
▸ Action Taken:	Drug withdrawn

5. Causality Assessment

Favipiravir - Acute allergic reaction

▸ Assessment by sponsor:	No assessment
▸ Assessment by investigator:	Reasonable possibility