

Report Overview - GB-MHRA-ESUSAR-215840426001-00111134

Submission Details

- Submitted by: Prof Gail Hayward
- Submission date: 29/09/2021

1. Trial Information

- Reference: NHS46631
- Trial Name: 2020-001209-22 PRINCIPLE - Platform Randomised trial of Interventions against COVID-19 In older peoPLE

2. Patient Details

- Patient initials: NHS46631
- Patient gender: Female
- Patient age at time of the side effect: 24 Years
- Patient Identification Number: NHS46631
- Patient weight (kg): 107.95

Obesity

- Continuing: Yes

AMOXICILLIN

- Start date: 09/08/2021

3. Suspect Reactions

Date sponsor was made aware of the SUSAR:
29/09/2021

Country of Origin:
United Kingdom

Narrative:

13th Aug 2021 - Randomisation to the trial. Pregnancy is an exclusion and participant made aware of contraception requirements during the day 1 safety call. 15th -18th Aug 2021 - Taking IMP (1800mg on day 1 and 800mg days 2-5). 22nd Aug 2021 - Positive pregnancy test at home. 6th Sept 2021 - Suffered from miscarriage during the 5th week of pregnancy. Participant has been using the contraceptive injection. First pregnancy. No parity. No medical conditions besides BMI at or above 35 kg/m2 and experiencing shortness of breath as part of COVID-19. Participant additionally started Amoxicillin on the 09/08/2021.

Seriousness

- Other

Miscarriage of pregnancy

- Reaction Outcome: Recovered
- Start date: 06/09/2021

Ultrasound antenatal screen

- Result: Confirmed miscarriage
- Test date: 13/09/2021

4. Suspect Medicines

Favipiravir (Avignan)

- Drug Characterisation: Suspect
- Drug Dosage: 800 Mg milligram(s)
- Drug Dosage Interval: 5 Days
- Form: Tablet
- Route of Administration: Oral
- Indication: COVID-19
- Start date: 15/08/2021
- End date: 18/08/2021
- Action Taken: Not applicable

AMOXICILLIN

- Drug Characterisation: Concomitant
- Start date: 09/09/2021

5. Causality Assessment

Favipiravir (Avignan) - Miscarriage of pregnancy

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