

## Report Overview - GB-MHRA-ESUSAR-215840423001-00108526

## Submission Details

- Submitted by: Prof Richard Haynes
- Submission date: 13/02/2021

## 1. Trial Information

- Reference: RECOVERY SUSAR 006
- 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: 15 Years
- Patient Identification Number: 1248202
- Patient weight (kg): 45

## Chromosome abnormality

- Start date: 01/2006
- Continuing: Yes

## Epilepsy

- Continuing: Yes

## 3. Suspect Reactions

Date sponsor was made aware of the SUSAR:  
12/02/2021

Country of Origin:  
United Kingdom

## Narrative:

14 year old boy with chromosome 18q mutation and epilepsy on invasive mechanical ventilation for COVID at the time of trial entry. Randomised to convalescent plasma on 6th January, then to tocilizumab in the second randomisation on 8th January. He was subsequently treated with iv co-amoxiclav from 23rd – 30th January, during which extravasation occurred. This developed into a subcutaneous abscess on 1st February that required further antibiotics and incision and drainage on 5th February. Immunosuppression caused by tocilizumab was a contributory factor in the opinion of the local investigators.

## Seriousness

- Hospitalisation

### Subcutaneous abscess

‣ Reaction Outcome:	Recovered
‣ Start date:	01/02/2021
‣ End date:	05/02/2021

## 4. Suspect Medicines

### TOCILIZUMAB

‣ Drug Characterisation:	Suspect
‣ Drug Dosage:	360 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Intravenous infusion
‣ Route of Administration:	Intravenous drip
‣ Indication:	COVID-19
‣ Start date:	01/01/2021
‣ Action Taken:	Not applicable

### PHENYTOIN SODIUM

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	115 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Oral solution
‣ Route of Administration:	Oral
‣ Indication:	Epilepsy
‣ Start date:	01/01/2021
‣ Action Taken:	Not applicable

### CLOBAZAM

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	20 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Oral solution
‣ Route of Administration:	Oral
‣ Indication:	Epilepsy
‣ Start date:	01/01/2021
‣ Action Taken:	Not applicable

### LACOSAMIDE

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	150 Mg milligram(s)
‣ Drug Dosage Interval:	12 Hours
‣ Form:	Oral solution
‣ Route of Administration:	Oral
‣ Indication:	Epilepsy
‣ Start date:	01/01/2021
‣ Action Taken:	Not applicable

### OMEPRAZOL

‣ Drug Characterisation:	Concomitant
‣ Drug Dosage:	20 Mg milligram(s)
‣ Drug Dosage Interval:	1 Days
‣ Form:	Oral solution
‣ Route of Administration:	Oral

▸ Indication:	Gastroesophageal reflux
▸ Start date:	01/01/2021
▸ Action Taken:	Not applicable

## 5. Causality Assessment

### TOCILIZUMAB - Subcutaneous abscess

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