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| Case Report Form |
| *Study Title* |
| Chief Investigator: |
| Sponsor: |
| JRES No°: |
| CRF Version No° and Date: |
| Screening No°: |
| Participant ID No° |
| I am confident that the information supplied in this case report form is complete and accurate.  I confirm that the study was conducted in accordance with the approved protocol and any approved protocol amendments.  I confirm that the written informed consent was obtained prior to study enrolment.  PI signature:  Date (dd/mm/yyyy): |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| |

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| **Informed Consent**  Informed consent **MUST** be given before any study specific procedures take place/any current therapy is discontinued for the purposes of participation in the study | | |
| Has the participant freely given informed consent? | Yes ❑ | No ❑ |
| Name of Person taking consent: | | |
| Date of consent (dd/mm/yyyy): |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| | | |
| Time of consent (hh:mm): |\_\_\_ \_\_\_|:|\_\_\_ \_\_\_| | | |

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| **Demographic Data** | | | |
| Age (yrs): \_\_\_ \_\_\_ \_\_\_ | Sex: | Male ❑ | Female ❑ |
| Height (m): \_\_\_ . \_\_\_ \_\_\_ | Weight (kg): | \_\_\_ \_\_\_ \_\_\_ . \_\_\_ | |

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| **Ethnicity** | | | |
| White British ❑ | White Irish ❑ | Other White background ❑ | Chinese ❑ |
| Asian or Asian British (Indian) ❑ | Asian or Asian British (Bangladeshi) ❑ | Asian or Asian British (Pakistani) ❑ | Other Asian Background ❑ |
| Black or Black British (African) ❑ | Black or Black British (Caribbean) ❑ | Other Black background ❑ | Other ❑  (Please specify): |

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| **INCLUSION CRITERIA**  **The following criteria MUST be answered YES for the participant to be eligible for the trial** | | |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
| **If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study.** | | |

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| **EXCLUSION CRITERIA**  **The following criteria MUST be answered NO for the participant to be eligible for the trial** | | |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
|  | Yes ❑ | No ❑ |
| **If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study.** | | |

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| Eligibility must be confirmed by the Principal Investigator/delegated co-investigator:  Name:  Signature:  Date (dd/mm/yyyy): |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| |

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| **Visit X**  Date of Visit: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| | |  | |
| Is the participant happy to continue? | | Yes ❑ No ❑ | |
| Allocated subject randomisation number:  \_\_\_ \_\_\_ \_\_\_ | |  | |
| Randomisation Arm | |  | |
| Arm 1 ❑ | Arm 2 ❑ | |  |

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| **Physical Examination** | |  | | | |  |
| System | Normal | | \*Abnormal | \*\*Not Done | If abnormal, please provide brief description and comment if clinically significant or not (CS/NCS) | |
| General Appearance | ❑ | | ❑ | ❑ |  | |
| Cardiovascular | ❑ | | ❑ | ❑ |  | |
| Respiratory | ❑ | | ❑ | ❑ |  | |
| Muscular-skeletal | ❑ | | ❑ | ❑ |  | |
| Neurological | ❑ | | ❑ | ❑ |  | |
| Joints | ❑ | | ❑ | ❑ |  | |
| Other(s) (please specify) | ❑ | | ❑ | ❑ |  | |

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| **Blood Results** | | | |
| WBC: | ESR: | Platelets: | |
| Haemoglobin: | CRP: | Bilirubin: | |
| Are any of the blood results abnormal/out of range?  If yes, PI should review:  Are the results clinically significant?  PI signature:  Date: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| | | | Yes ❑ No ❑  Yes ❑ No ❑ |

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| Has the completion of the diary card been explained to the participant? | Yes ❑ No ❑ |
| Has a prescription been completed and sent to pharmacy? | Yes ❑ No ❑ |
| Has medication been collected from pharmacy? | Yes ❑ No ❑ |

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| PI signature:  Date: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| |  |
| CRF completed by (signature):  Date: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| |  |

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| **CONCOMITANT MEDICATIONS** | | | | | | |
| Medication | Indication | Dose and Frequency | Route of Administration | Start Date  (dd/mm/yyyy) | Stop Date  (dd/mm/yyyy) | Ongoing |
|  |  |  |  |  |  | ❑ |
|  |  |  |  |  |  | ❑ |
|  |  |  |  |  |  | ❑ |
|  |  |  |  |  |  | ❑ |

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| **MEDICAL HISTORY** | | | |
| Condition | Onset date  dd/mm/yyyy | End date  dd/mm/yyyy | Ongoing |
|  |  |  | ❑ |
|  |  |  | ❑ |
|  |  |  | ❑ |
|  |  |  | ❑ |
|  |  |  | ❑ |
|  |  |  | ❑ |

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| **END OF TRIAL** | | | |
| Did the participant complete the trial? | | | Yes ❑ No ❑ |
| If yes, date of last visit: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| | | |  |
| If no, date of withdrawal: |\_\_\_ \_\_\_| |\_\_\_ \_\_\_| 20 |\_\_\_ \_\_\_| | | |  |
| **Early Withdrawal** | | |  |
| Please select the most appropriate reason for the participant not completing the trial: | | | |
| Participant’s decision | ❑ | Investigator’s decision | ❑ |
| Lost to Follow Up | ❑ | Death | ❑ |
| Adverse Events Related *Please state related AE:* | ❑ | Other  *Please specify:* | ❑ |