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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 datedd/mm/yyyy | End datedd/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:* | ❑ |