**S3 Table: Study schedule of events.**

| Assessments | Screening/Run in | Study Period 1  |
| --- | --- | --- |
| Visit 1 | Visit 2 | Visit 3  | Visit 4 | Visit 5 | Visit 6 | Visit 7 | Visit 8 | Visit 9 | Visit 10  | Visit 11 | Visit 12 | Visit 13 | Visit 14 |
| Day -46 to -73 | Day -45 | Day -43 | Day -38 | Baseline D0 | D7 | D28 | D35 | W8 | W8 +48 hours | W9 | W12 | W15 | W19 |
| Informed consent | X |   |  |  |   |   |   |   |   |  |   |  |  |   |
| Review inclusion/exclusion criteria | X |   |  |  | X |   |   |   |   |  |   |  |  |   |
| Demographics, Medical/Surgical History | X |   |  |  |   |   |   |   |   |  |   |  |  |   |
| Physical Examination (symptom directed) | X |   |  |  | (X) | (X) | (X) | (X) | (X) | (X) | (X) | (X) | (X) |  |
| Vital signs/Body Weight/Height  | X |   |  |  | X |  | X |  | X |  |  | X |  |  |
| Electrocardiogram | X |   |  |  |   |   |   |   |   |  |   |  |  |   |
| Urine Pregnancy Test | X |   |  |  | X |   | X |   | X |  |   |  |  |   |
| Haematology | X |   |  |  | X | X | X | X | X |  | X | X |  |   |
| Chemistry | X |   |  |  | X | X | X | X | X |  | X | X |  |   |
| Coagulation | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Urinalysis | X |   |  |  | X |   | X |   | X |  |   |  |  |   |
| Viral Serology (HIV, Hepatitis B and C, HSV-1 and  | X |   |  |  |   |   |   |   |   |  |   |  |  |   |
| ELISA (antibody) |  |  |  |  | X |  | X |  | X |  |  | X |  |  |
| ELIspot (T-cell) |   |   |  |  | X | X |   | X |   |  | X |  |  |   |
| Exploratory Immune assays (T-cell and/or genetic testing) |   |   |  |  |  X |  |   |   |  X |  | X  |  |  |   |
| Randomization |   |   |  |  | X |   |   |   |   |  |   |  |  |   |
| Phone call |  |  | X | X |  |  |  |  |  |  |  |  |  | X |
| Study vaccine administration and bleb check/measurement |  |  |  |  | X |  | X |  | X |  |  |  |  |  |
| Collection of daily swabs from mucocutaneous genital sites for viral shedding for 45 days |  | X |  |  |  |  |  |  |  |  | X |  |  |  |
| Take photos of injection site reactions |  |  |  |  |  | X |  | X |  | X |  |  |  |  |
| Issue and collect Diary |  | X |  |  | X | X | X | X | X |  | X |  | X |  |
| Review diary cards for compliance and adverse events. |  |  | X | X | X | X |  | X |  | X | X | X | X |  |
| Optional skin biopsy |  |  |  |  |  |  |  |  |  | X |  |  |  |  |
| Patient education regarding swab collection, diary completion and outbreak management |  | X | X | X |  |  |  |  |  |  | X | X |  |  |
| Adverse Event and Outbreak assessment |  | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Concurrent Medications | X | X | X | X | X | X | X | X | X | X | X | X | X | X |

| Assessments | Study Period 2 | Follow up |
| --- | --- | --- |
| Visit 15 | Visit 16 | Visit 17 | Visit 18 | Visit 19 | Visit 20 | Visit 21 | Visit 22 |
| W23 | W24 | W25 | W28 | W31 | W36 | W42 | End of Study/ W48 |
| Informed consent |   |   |   |  |   |   |   |   |
| Review inclusion/exclusion criteria |   |   |   |  |   |   |   |   |
| Demographics, Medical/Surgical History |   |   |   |  |   |   |   |   |
| Physical Examination (symptom directed) | (X) | (X) | (X) | (X) | (X) |   |   | (X) |
| Vital signs/Body Weight/Height  |  | X |  | X |  |   |   | X |
| Electrocardiogram |   |   |   |  |   |   |   |  |
| Urine Pregnancy Test |   | X |   |  |   |   |   | X |
| Hematology  | X | X | X | X |   |   |   | X |
| Chemistry | X | X | X | X |   |   |   | X |
| Coagulation |  |  |  |  |  |  |  |  |
| Urinalysis |   | X |   |  |   |   |   | X |
| Viral Serology (HIV, Hepatitis B and C, HSV-1 and 2) |   |   |   |  |   |   |   |   |
| Competitive Inhibition ELISA (antibody) |  | X |  | X |  |  |  | X |
| ELIspot (T cell) |   | X | X |  |   |   |   | X |
| Exploratory Immune assays (T cell and/or genetic testing) |   | X | X |  |   |   |   | X |
| Randomization |   |   |   |  |   |   |   |   |
| Phone call |   |   |   |  |   | X | X |   |
| Study vaccine administration and bleb check/measurement |   | X |   |  |   |   |   |   |
| Collection of daily swabs from mucocutaneous genital sites for viral shedding for 45 days |   |   | X |  |   |   |   |   |
| Take photos of injection site (s) |  |  | X |  |  |  |  |  |
| Issue and collect Diary |   | X | X |  | X |   |   |  |
| Review diary cards for compliance and adverse events. |  |  | X | X | X |   |   |  |
| Skin biopsy |  |  |  |  |  |  |  |  |
| Patient education regarding swab collection, diary completion and outbreak management |   |   | X | X |   |   |   |   |
| Adverse Event and Outbreak assessment | X | X | X | X | X | X | X | X |
| Concurrent Medications | X | X | X | X | X | X | X | X |