



Clinical trial results:

Observer blinded, randomised study to investigate safety, tolerability and long-term immunogenicity of different dose regimens and formulations of MV-CHIK in healthy volunteers

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2018-000211-25 |
| Trial protocol | GB |
| Global end of trial date | 16 November 2019 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v2 (current) |
| This version publication date | 10 November 2021 |
| First version publication date | 09 September 2021 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | V184-005 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|--|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03635086 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | MV-CHIK-205: Themisbio, 2018-000211-25: EudraCT Number |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 16 November 2019 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 25 January 2019 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 November 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to investigate immunogenicity and safety of Measles Virus-Chikungunya (MV-CHIK) in different dose regimens, 28 days after one or two vaccinations.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

| | |
|---|----------------|
| Actual start date of recruitment | 22 August 2018 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United Kingdom: 60 |
| Worldwide total number of subjects | 60 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|----|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 60 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

After completion of screening procedures, participants will be randomized to one of five treatment groups (A, B, C, D or E).

Period 1

| | |
|------------------------------|--|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Assessor |

Arms

| | |
|------------------------------|---|
| Are arms mutually exclusive? | Yes |
| Arm title | Group A: Two MV-CHIK Lyophilized Low Dose |

Arm description:

Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, lyophilized low dose (powder for suspension in water for intramuscular [IM] injection): $5 \times 10^4 \pm 0.5$ log tissue culture infectious dose 50 (TCID50)/dose.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | MV-CHIK lyophilised formulation, low dose |
| Investigational medicinal product code | MV-CHIK |
| Other name | V184 |
| Pharmaceutical forms | Powder for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, lyophilized low dose (powder for suspension in water for intramuscular [IM] injection): $5 \times 10^4 \pm 0.5$ log tissue culture infectious dose 50 (TCID50)/dose

| | |
|------------------|---|
| Arm title | Group B: Two MV-CHIK Liquid Frozen Low Dose |
|------------------|---|

Arm description:

Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | MV-CHIK liquid frozen formulation, low dose |
| Investigational medicinal product code | MV-CHIK |
| Other name | V184 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose.

| | |
|------------------|---|
| Arm title | Group C: Two MV-CHIK Liquid Low Dose SPS® |
|------------------|---|

Arm description:

Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid SPS® low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose.

| | |
|--|------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | MV-CHIK SPS® formulation, low dose |
| Investigational medicinal product code | MV-CHIK |
| Other name | V184 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid SPS® low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5 \log$ TCID50/dose.

| | |
|------------------|--|
| Arm title | Group D: Two MV-CHIK Liquid Frozen High Dose |
|------------------|--|

Arm description:

Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5 \log$ TCID50/dose.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MV-CHIK liquid frozen formulation, high dose |
| Investigational medicinal product code | MV-CHIK |
| Other name | V184 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5 \log$ TCID50/dose.

| | |
|------------------|--|
| Arm title | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|------------------|--|

Arm description:

Participants received one vaccination (Day 0) with MV-CHIK a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5 \log$ TCID50/dose and placebo (Day 28), a sterile physiological saline solution (0.9% sodium chloride [NaCl]), administered by IM injection.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | MV-CHIK liquid frozen formulation high dose/placebo |
| Investigational medicinal product code | MV-CHIK/Placebo |
| Other name | V184 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose. Placebo was sterile physiological saline solution (0.9% sodium chloride [NaCl]), administered by IM injection.

| | |
|--|--|
| Investigational medicinal product name | MV-CHIK liquid frozen formulation, high dose |
| Investigational medicinal product code | MV-CHIK |
| Other name | V184 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5 \log$ TCID50/dose.

| Number of subjects in period 1 | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® |
|---------------------------------------|---|---|---|
| Started | 12 | 12 | 12 |
| Completed | 11 | 11 | 11 |
| Not completed | 1 | 1 | 1 |
| Consent withdrawn by subject | - | - | 1 |
| Adverse event, non-fatal | - | 1 | - |
| Lost to follow-up | 1 | - | - |

| Number of subjects in period 1 | Group D: Two MV-CHIK Liquid Frozen High Dose | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|---------------------------------------|--|--|
| Started | 12 | 12 |
| Completed | 12 | 12 |
| Not completed | 0 | 0 |
| Consent withdrawn by subject | - | - |
| Adverse event, non-fatal | - | - |
| Lost to follow-up | - | - |

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | Group A: Two MV-CHIK Lyophilized Low Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, lyophilized low dose (powder for suspension in water for intramuscular [IM] injection): $5 \times 10^4 \pm 0.5$ log tissue culture infectious dose 50 (TCID50)/dose. | |
| Reporting group title | Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid SPS® low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group D: Two MV-CHIK Liquid Frozen High Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Reporting group description: Participants received one vaccination (Day 0) with MV-CHIK a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5$ log TCID50/dose and placebo (Day 28), a sterile physiological saline solution (0.9% sodium chloride [NaCl]), administered by IM injection. | |

| Reporting group values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® |
|---|---|---|---|
| Number of subjects | 12 | 12 | 12 |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age Continuous Units: years | | | |
| arithmetic mean | 37.9 | 34.6 | 39.0 |
| standard deviation | ± 9.52 | ± 11.79 | ± 11.60 |

| | | | |
|---|----|----|----|
| Sex: Female, Male Units: Participants | | | |
| Female | 3 | 4 | 4 |
| Male | 9 | 8 | 8 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 12 | 12 | 12 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

| Reporting group values | Group D: Two MV-CHIK Liquid Frozen High Dose | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | Total |
|--|--|--|-------|
| Number of subjects | 12 | 12 | 60 |
| Age categorical Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age Continuous Units: years | | | |
| arithmetic mean | 36.3 | 36.8 | |
| standard deviation | ± 9.62 | ± 7.52 | - |
| Sex: Female, Male Units: Participants | | | |
| Female | 6 | 6 | 23 |
| Male | 6 | 6 | 37 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 12 | 12 | 60 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | Group A: Two MV-CHIK Lyophilized Low Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, lyophilized low dose (powder for suspension in water for intramuscular [IM] injection): $5 \times 10^4 \pm 0.5$ log tissue culture infectious dose 50 (TCID50)/dose. | |
| Reporting group title | Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid SPS® low dose (suspension for IM injection): $1 \times 10^5 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group D: Two MV-CHIK Liquid Frozen High Dose |
| Reporting group description: Participants received two vaccinations (Day 0 and Day 28) with MV-CHIK, a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5$ log TCID50/dose. | |
| Reporting group title | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Reporting group description: Participants received one vaccination (Day 0) with MV-CHIK a live-attenuated recombinant measles vaccine expressing Chikungunya virus antigens, liquid frozen high dose (suspension for IM injection): $1 \times 10^6 \pm 0.5$ log TCID50/dose and placebo (Day 28), a sterile physiological saline solution (0.9% sodium chloride [NaCl]), administered by IM injection. | |

Primary: Geometric Mean Titer of Anti-Chikungunya Antibodies as Measured by 50% Plaque Reduction Neutralization Test 28 Days After Last MV-CHIK Vaccination

| | |
|--|--|
| End point title | Geometric Mean Titer of Anti-Chikungunya Antibodies as Measured by 50% Plaque Reduction Neutralization Test 28 Days After Last MV-CHIK Vaccination |
| End point description: Participant serum was collected for determination of antibody responses by 50% plaque reduction neutralization test (PRNT50). Geometric Mean Titer (GMT) of functional antibodies as measured by PRNT50 were assessed. Geometric mean titers and GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2 sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey Kramer. The analysis population included all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. | |
| End point type | Primary |
| End point timeframe: 28 days after last vaccination (Up to Day 56) | |

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|--|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 11 | 9 | 11 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | 21.0 (9.9 to 44.5) | 19.1 (9.0 to 40.5) | 13.6 (5.9 to 31.2) | 45.7 (21.6 to 97.0) |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|--|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | 8.9 (4.2 to 18.8) | | | |

Statistical analyses

| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|----------------------------|--|
|----------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9998 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 4.9 |

| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|----------------------------|--|
|----------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point

estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9345 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 7.5 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5836 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.1 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|-------------------|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|-------------------|--|

| | |
|---|-------------------------------|
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.4844 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 10.6 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9725 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 6.8 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|-------------------|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|-------------------|--|

| | |
|---|-------------------------------|
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5969 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 9.6 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.4715 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.9 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|-------------------|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|-------------------|--|

| | |
|---|-------------------------------|
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9388 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 7.4 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 20 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.2043 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.4 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chikungunya Antibodies by PRNT50- 28 days |
|-----------------------------------|--|

Statistical analysis description:

GMT ratios were estimated by applying an analysis of variance (ANOVA) including the factor treatment group. This was done using log10 transformed data and taking the anti-log of the resulting point estimates for the least squares means, least squares means differences and the corresponding 2-sided 95% confidence intervals (CI). P-values were also provided to compare GMTs between treatment groups adjusted for multiple comparisons according to Tukey-Kramer.

| | |
|-------------------|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
|-------------------|---|

| | |
|---|-------------------------------|
| Number of subjects included in analysis | 22 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0251 |
| Method | Tukey-Kramer |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 5.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.2 |
| upper limit | 23.1 |

Secondary: Percentage of Participants with Solicited and Unsolicited Adverse Events

| | |
|-----------------|--|
| End point title | Percentage of Participants with Solicited and Unsolicited Adverse Events |
|-----------------|--|

End point description:

An adverse event (AE) includes any untoward medical occurrence in a participant to whom an IMP has been administered, not necessarily caused by or related to that product. An AE can therefore be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease temporally associated with the use of an IMP whether or not considered related to the IMP. The percentage of participants with solicited and unsolicited AEs was assessed. The analysis population included all participants who entered in the study and received at least one IMP administration. All analyses based on the safety population were carried out using the actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-----------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 83.3 | 91.7 | 58.3 | 83.3 |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|-----------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 91.7 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with at Least 1 Serious Adverse Event

| | |
|-----------------|--|
| End point title | Percentage of Participants with at Least 1 Serious Adverse Event |
|-----------------|--|

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, and consists of a congenital anomaly, birth defect or other important medical events. The analysis population included all participants who entered in the study and received at least one IMP administration. All analyses based on the safety population were carried out using the actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-----------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 0.0 | 0.0 | 0.0 | 0.0 |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|-----------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 0.0 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer of Anti-Chikungunya Antibodies as Measured by PRNT50

| | |
|---|---|
| End point title | Geometric Mean Titer of Anti-Chikungunya Antibodies as Measured by PRNT50 |
| End point description: | |
| Participant serum was collected at each visit (Day 0, 28, 56, 182, and 365) for determination of antibody response by PRNT50. These results represent geometric mean titers (titers <10 were set to 5 for protocol-specified analysis). The analysis population included all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Day 365 | |

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|--|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 5.0 (3.0 to 8.2) | 8.6 (5.3 to 14.2) | 5.0 (3.0 to 8.4) | 5.0 (3.0 to 8.2) |
| Day 28 (n=11, 11, 10, 11, 11) | 7.2 (3.9 to 13.2) | 14.0 (7.6 to 25.6) | 6.3 (3.4 to 11.9) | 11.3 (6.2 to 20.8) |
| Day 56 (n=11, 11, 9, 11, 11) | 21.0 (10.1 to 43.7) | 19.1 (9.2 to 39.7) | 13.6 (6.0 to 30.5) | 45.7 (22.0 to 95.2) |
| Day 182 (n=11, 11, 10, 11, 11) | 13.8 (7.0 to 27.2) | 18.2 (9.2 to 35.9) | 10.5 (5.1 to 21.5) | 11.8 (6.0 to 23.4) |
| Day 365 (n=10, 11, 9, 11, 11) | 7.2 (3.9 to 13.6) | 11.8 (6.5 to 21.5) | 8.9 (4.6 to 17.2) | 8.3 (4.6 to 15.0) |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|--|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 5.0 (3.0 to 8.2) | | | |
| Day 28 (n=11, 11, 10, 11, 11) | 8.9 (4.8 to 16.2) | | | |
| Day 56 (n=11, 11, 9, 11, 11) | 6.9 (3.3 to 14.3) | | | |
| Day 182 (n=11, 11, 10, 11, 11) | 6.8 (3.4 to 13.5) | | | |
| Day 365 (n=10, 11, 9, 11, 11) | 5.0 (2.8 to 9.1) | | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 1.6 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.8 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups | |

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.7 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.7 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.55 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 4.7 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 4.6 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 4.6 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 0) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.8 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 0)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.8 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 0)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 2.7 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5321 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 1.7 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9983 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9882 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 2.7 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 28)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8234 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 2.1 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 28)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.3778 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 7.6 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9878 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.1 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8213 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 5.3 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 28) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.6716 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 1.9 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 28)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.938 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 2.5 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 28)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9777 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.3 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9287 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 7.2 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9997 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 4.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5598 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 56)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.2117 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 13.1 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 56)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9699 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 6.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.292 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 11.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.446 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 56) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.184 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.4 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 56)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7229 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 9.2 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 56)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0052 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 6.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.5 |
| upper limit | 28.6 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9777 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 3 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9812 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 5.3 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9979 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 4.5 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 182)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7973 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 7 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 182)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.588 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 7.9 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.2602 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 10.4 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8992 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 6 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9991 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 3.6 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 182)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9028 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 6.2 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9915 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.8 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 2.9 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 365) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7833 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 2.1 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7761 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 6.8 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 365) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.998 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.909 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.9 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9651 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.7 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 365) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9112 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 4.7 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 365) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9999 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.8 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by PRNT50- 365 days (Day 365) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.6953 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 6.2 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.257 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 7.8 |

Statistical analysis title

Anti-Chik Antibodies by PRNT50- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7523 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 5.4 |

Secondary: Percentage of CD4+CD69+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|---|
| End point title | Percentage of CD4+CD69+ Chikungunya Virus Specific T- |
|-----------------|---|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+CD69+ (Day 0) | 0.0194 (± 0.0446) | | | |
| CD4+CD69+ (Day 14) | 0.1430 (± 0.1589) | | | |
| CD4+CD69+ (Day 28) | 0.1077 (± 0.2060) | | | |
| CD4+CD69+ (Day 42) | 0.2050 (± 0.2316) | | | |
| CD4+CD69+ (Day 56) | 0.1935 (± 0.2036) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD4+CD69+CD137+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|---|
| End point title | Percentage of CD4+CD69+CD137+ Chikungunya Virus Specific T-Cells ^[2] |
|-----------------|---|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, a subset of the participants in treatment group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+CD69+CD137+ (Day 0) | 0.0061 (± 0.0112) | | | |
| CD4+CD69+CD137+ (Day 14) | 0.0174 (± 0.0313) | | | |
| CD4+CD69+CD137+ (Day 28) | 0.0120 (± 0.0168) | | | |
| CD4+CD69+CD137+ (Day 42) | 0.0317 (± 0.0438) | | | |
| CD4+CD69+CD137+ (Day 56) | 0.0393 (± 0.0476) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD4+CD137+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|--|
| End point title | Percentage of CD4+CD137+ Chikungunya Virus Specific T- |
|-----------------|--|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+CD137+ (Day 0) | 0.0528 (± 0.0509) | | | |
| CD4+CD137+ (Day 14) | 0.1595 (± 0.2105) | | | |
| CD4+CD137+ (Day 28) | 0.1492 (± 0.0932) | | | |
| CD4+CD137+ (Day 42) | 0.3484 (± 0.3428) | | | |
| CD4+CD137+ (Day 56) | 0.3994 (± 0.2713) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD4+CD69+OX40+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|--|
| End point title | Percentage of CD4+CD69+OX40+ Chikungunya Virus Specific T-Cells ^[4] |
|-----------------|--|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+CD69+OX40+ (Day 0) | 0.0033 (± 0.0048) | | | |
| CD4+CD69+OX40+ (Day 14) | 0.0265 (± 0.0522) | | | |
| CD4+CD69+OX40+ (Day 28) | 0.0095 (± 0.0070) | | | |
| CD4+CD69+OX40+ (Day 42) | 0.0267 (± 0.0408) | | | |
| CD4+CD69+OX40+ (Day 56) | 0.0337 (± 0.0386) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD4+OX40+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|---|
| End point title | Percentage of CD4+OX40+ Chikungunya Virus Specific T- |
|-----------------|---|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD4+OX40+ (Day 0) | 0.0062 (± 0.0158) | | | |
| CD4+OX40+ (Day 14) | 0.0745 (± 0.1007) | | | |

| | | | | |
|--------------------|-------------------|--|--|--|
| CD4+OX40+ (Day 28) | 0.0269 (± 0.0280) | | | |
| CD4+OX40+ (Day 42) | 0.0492 (± 0.1012) | | | |
| CD4+OX40+ (Day 56) | 0.0698 (± 0.0997) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD8+CD69+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|---|
| End point title | Percentage of CD8+CD69+ Chikungunya Virus Specific T- |
|-----------------|---|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD8+CD69+ (Day 0) | 0.1919 (± 0.2329) | | | |
| CD8+CD69+ (Day 14) | 0.3319 (± 0.6046) | | | |
| CD8+CD69+ (Day 28) | 0.4242 (± 0.6330) | | | |
| CD8+CD69+ (Day 42) | 0.1961 (± 0.2496) | | | |
| CD8+CD69+ (Day 56) | 0.2375 (± 0.2902) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD8+CD69+CD137+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|---|
| End point title | Percentage of CD8+CD69+CD137+ Chikungunya Virus Specific T-Cells ^[7] |
|-----------------|---|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | | | | |
|--------------------------------------|--|--|--|--|
| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD8+CD69+CD137+ (Day 0) | 0.0005 (± 0.0018) | | | |
| CD8+CD69+CD137+ (Day 14) | 0.0139 (± 0.0229) | | | |
| CD8+CD69+CD137+ (Day 28) | 0.0184 (± 0.0454) | | | |
| CD8+CD69+CD137+ (Day 42) | 0.0148 (± 0.0171) | | | |
| CD8+CD69+CD137+ (Day 56) | 0.0380 (± 0.0392) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of CD8+CD137+ Chikungunya Virus Specific T-Cells

| | |
|-----------------|--|
| End point title | Percentage of CD8+CD137+ Chikungunya Virus Specific T- |
|-----------------|--|

End point description:

Cellular immunogenicity was determined by the evaluation of T cell immune response. Blood was collected for the isolation of peripheral blood mononuclear cells (PBMCs). PBMCs were isolated from whole blood to determine functional Interleukin 2 (IL-2)-producing T cells on day 0, 14, 28, 42, and 56 and in a subset of participants. The analysis population included a subset of all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response. Based on the protocol, only

participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Based on the protocol, only participants in subset Treatment Group D (MV-CHIK liquid frozen high dose formulation) were analyzed for t-cell response.

| End point values | Group D: Two MV-CHIK Liquid Frozen High Dose | | | |
|--------------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Percentage of t-cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| CD8+CD137+ (Day 0) | 0.0194 (± 0.0334) | | | |
| CD8+CD137+ (Day 14) | 0.0294 (± 0.0366) | | | |
| CD8+CD137+ (Day 28) | 0.0224 (± 0.0377) | | | |
| CD8+CD137+ (Day 42) | 0.0341 (± 0.0595) | | | |
| CD8+CD137+ (Day 56) | 0.0607 (± 0.0557) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titer of Anti-Chikungunya Antibodies Determined by Enzyme Linked Immunosorbent Assay

| | |
|-----------------|---|
| End point title | Geometric Mean Titer of Anti-Chikungunya Antibodies Determined by Enzyme Linked Immunosorbent Assay |
|-----------------|---|

End point description:

Participant serum was collected at each visit (Day 0, 28, 56, 182, and 365) for determination of Chikungunya antibody response by enzyme linked immunosorbent assay (ELISA). The analysis population included all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 365

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Titer | | | | |
| geometric mean (standard deviation) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 7.4 (± 0.0) | 14.5 (± 3907.50) | 7.4 (± 0.0) | 7.4 (± 0.0) |
| Day 28 (n=11, 11, 10, 11, 11) | 9.7 (± 46.83) | 17.8 (± 4009.38) | 8.1 (± 3.69) | 14.1 (± 28.47) |
| Day 56 (n=11, 11, 10, 11, 11) | 54.3 (± 306.39) | 90.0 (± 4369.43) | 54.7 (± 112.29) | 171.4 (± 307.41) |
| Day 182 (n=11, 11, 10, 11, 11) | 15.6 (± 112.90) | 26.9 (± 3304.35) | 16.3 (± 92.58) | 26.5 (± 17.36) |
| Day 365 (n=10, 11, 9, 11, 11) | 11.9 (± 112.80) | 23.8 (± 3087.93) | 15.8 (± 75.39) | 18.9 (± 18.52) |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|-------------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Titer | | | | |
| geometric mean (standard deviation) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 7.4 (± 0.0) | | | |
| Day 28 (n=11, 11, 10, 11, 11) | 13.1 (± 8.74) | | | |
| Day 56 (n=11, 11, 10, 11, 11) | 9.8 (± 7.69) | | | |
| Day 182 (n=11, 11, 10, 11, 11) | 8.1 (± 4.66) | | | |
| Day 365 (n=10, 11, 9, 11, 11) | 9.4 (± 10.01) | | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.7 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.5 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.4 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 0)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.5 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 0)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 6.7 |

| | |
|---|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.55 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 7 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5263 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 6.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 0) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.4 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 0)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 3.5 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 28)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7708 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.4 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9503 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 3 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9791 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 3.2 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
|-----------------------------------|--|

| | |
|--|---|
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.5739 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 9.8 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9966 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 5.4 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9748 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 5.9 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.827 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.6 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9918 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 5.4 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.893 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.8 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 28) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9999 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 4.7 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9105 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3.2 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 5.5 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9213 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 9.1 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
|-----------------------------------|--|

| | |
|--|--|
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8092 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.8 |

| | |
|---|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0423 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 5.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 29.2 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.3047 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.7 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.004 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 9.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.7 |
| upper limit | 48.5 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0001 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 17.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.3 |
| upper limit | 92.2 |

| | |
|-----------------------------------|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 56) |
|-----------------------------------|--|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.0488 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 5.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 30.7 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 56)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.3347 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 1.8 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 182)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8831 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.8916 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3.1 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 5.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
|-----------------------------------|---|

| | |
|--|--|
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.2563 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 3.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 17.1 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 1 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 5.2 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9169 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.6 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 8.9 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.794 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 9.9 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7708 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 10.8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 182) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9237 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3.3 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 182)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.2661 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 3.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 16.9 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group B: Two MV-CHIK Liquid Frozen Low Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7614 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.5 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 2.6 |

| | |
|--|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9905 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 4.3 |

| | |
|--|--|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
| Statistical analysis description: | |
| Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups. | |
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.933 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3.3 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group A: Two MV-CHIK Lyophilized Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9945 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 6.7 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group C: Two MV-CHIK Liquid Low Dose SPS® |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9599 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 8.4 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9942 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 6.4 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group B: Two MV-CHIK Liquid Frozen Low Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.4932 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.5 |
| upper limit | 12.9 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group D: Two MV-CHIK Liquid Frozen High Dose |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9983 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 4.6 |

| | |
|-----------------------------------|---|
| Statistical analysis title | Anti-Chik Antibodies by ELISA- 365 days (Day 365) |
|-----------------------------------|---|

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|---|
| Comparison groups | Group D: Two MV-CHIK Liquid Frozen High Dose v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.7431 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.4 |
| upper limit | 10.2 |

Statistical analysis title

Anti-Chik Antibodies by ELISA- 365 days (Day 365)

Statistical analysis description:

Analysis of variance (ANOVA) for GMT of Chikungunya-ELISA antibodies between treatment groups.

| | |
|---|--|
| Comparison groups | Group C: Two MV-CHIK Liquid Low Dose SPS® v Group E: One MV-CHIK Liquid Frozen High Dose/Placebo |
| Number of subjects included in analysis | 24 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.9112 |
| Method | ANOVA |
| Parameter estimate | Geometric Mean Ratio Estimate |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.3 |
| upper limit | 9.3 |

Secondary: Geometric Mean Titer of Anti-Measles Antibodies Determined by ELISA

| | |
|-----------------|---|
| End point title | Geometric Mean Titer of Anti-Measles Antibodies Determined by ELISA |
|-----------------|---|

End point description:

Participant serum was collected at each visit (Day 0, 28, and 56) for determination of antibody responses by ELISA. The analysis population included all randomized participants who received at least one investigational medicinal product (IMP) administration and had no major protocol deviation that could have had an impact on their immune response.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-------------------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 11 | 11 | 10 | 11 |
| Units: Titer | | | | |
| geometric mean (standard deviation) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 711.6 (± 1764.77) | 482.1 (± 1009.40) | 750.2 (± 1580.90) | 731.0 (± 1612.98) |
| Day 28 (n=11, 11, 10, 11, 11) | 1250.8 (± 1629.35) | 1120.3 (± 849.01) | 1207.7 (± 1642.33) | 2246.4 (± 1515.40) |
| Day 56 (n=11, 11, 10, 11, 11) | 1476.8 (± 1672.10) | 1158.6 (± 1019.59) | 1355.4 (± 1818.08) | 3009.8 (± 1355.67) |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|-------------------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 11 | | | |
| Units: Titer | | | | |
| geometric mean (standard deviation) | | | | |
| Day 0 (n=11, 11, 10, 11, 11) | 888.4 (± 1560.14) | | | |
| Day 28 (n=11, 11, 10, 11, 11) | 2116.2 (± 1527.25) | | | |
| Day 56 (n=11, 11, 10, 11, 11) | 2011.8 (± 1852.26) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Abnormal Laboratory Hematology Values Reported as an AE

| | |
|-----------------|---|
| End point title | Number of Participants With Abnormal Laboratory Hematology Values Reported as an AE |
|-----------------|---|

End point description:

An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study. Abnormal laboratory hematology value was any AE reported under the System Organ Class of Investigations that was related to an abnormal laboratory hematology value. The analysis population included all participants who entered in the study and received at least one IMP administration. All analyses based on the safety population were carried out using the actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-----------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | 1 | 0 | 0 | 0 |

| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Participants | 4 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Abnormal Laboratory Chemistry Values Reported as an AE

| | |
|-----------------|--|
| End point title | Number of Participants With Abnormal Laboratory Chemistry Values Reported as an AE |
|-----------------|--|

End point description:

An AE is defined as any unfavorable and unintended sign including an abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure, that occurs during the course of the study. Abnormal laboratory chemistry value was any AE reported under the System Organ Class of Investigations that was related to an abnormal laboratory chemistry value. The analysis population included all participants who entered in the study and received at least one IMP administration. All analyses based on the safety population were carried out using the actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 56

| End point values | Group A: Two MV-CHIK Lyophilized Low Dose | Group B: Two MV-CHIK Liquid Frozen Low Dose | Group C: Two MV-CHIK Liquid Low Dose SPS® | Group D: Two MV-CHIK Liquid Frozen High Dose |
|-----------------------------|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | 0 | 1 | 0 | 1 |

| | | | | |
|-----------------------------|---|--|--|--|
| End point values | Group E: One MV-CHIK Liquid Frozen High Dose/Placebo | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 12 | | | |
| Units: Participants | 0 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious and non-serious adverse events: Up to ~Day 56. All cause mortality: Up to ~Day 365.

Adverse event reporting additional description:

The analysis population included all participants who entered in the study and received at least one IMP administration. As per the protocol, adverse events were analyzed per treatment group but were not assessed with respect to individual vaccinations.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 22.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------|
| Reporting group title | Group A |
|-----------------------|---------|

Reporting group description:

Participants received two vaccinations with MV-CHIK lyophilized formulation, low dose on day 0 and day 28.

| | |
|-----------------------|---------|
| Reporting group title | Group B |
|-----------------------|---------|

Reporting group description:

Participants received two vaccinations with MV-CHIK liquid low dose frozen formulation on day 0 and day 28.

| | |
|-----------------------|---------|
| Reporting group title | Group C |
|-----------------------|---------|

Reporting group description:

Participants received two vaccinations with MV-CHIK liquid low dose SPS® formulation on day 0 and day 28.

| | |
|-----------------------|---------|
| Reporting group title | Group D |
|-----------------------|---------|

Reporting group description:

Participants received two vaccinations with MV-CHIK liquid frozen high dose formulation on day 0 and day 28.

| | |
|-----------------------|---------|
| Reporting group title | Group E |
|-----------------------|---------|

Reporting group description:

Participants received one vaccination with MV-CHIK liquid frozen high dose formulation on day 0 and placebo on day 28.

| Serious adverse events | Group A | Group B | Group C |
|---|----------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |

| Serious adverse events | Group D | Group E | |
|---|----------------|----------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from | | | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | Group A | Group B | Group C |
|---|------------------|------------------|-----------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 12 (83.33%) | 11 / 12 (91.67%) | 7 / 12 (58.33%) |
| Vascular disorders | | | |
| Pallor | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 2 | 1 |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | 2 / 12 (16.67%) |
| occurrences (all) | 1 | 1 | 3 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | 2 / 12 (16.67%) |
| occurrences (all) | 1 | 1 | 3 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 2 / 12 (16.67%) |
| occurrences (all) | 0 | 1 | 3 |
| Injection site induration | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Injection site pain | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 3 / 12 (25.00%) | 3 / 12 (25.00%) |
| occurrences (all) | 3 | 5 | 6 |
| Injection site pruritus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 2 |
| Injection site swelling | | | |

| | | | |
|---|----------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 3 |
| Pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Reproductive system and breast disorders Vulvovaginal pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 3 / 12 (25.00%) 3 | 0 / 12 (0.00%) 0 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 1 / 12 (8.33%) 1 | 1 / 12 (8.33%) 1 |
| Productive cough subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Sinus pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| White blood cell count decreased | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nervous system disorders | | | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 2 / 12 (16.67%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 2 | 1 |
| Headache | | | |
| subjects affected / exposed | 5 / 12 (41.67%) | 5 / 12 (41.67%) | 5 / 12 (41.67%) |
| occurrences (all) | 8 | 7 | 7 |
| Paraesthesia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Syncope | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 1 | 1 |
| Blood and lymphatic system disorders | | | |
| Eosinophilia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Anaemia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Excessive cerumen production | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|--|--|---|
| <p>Eye disorders</p> <p>Lacrimation increased</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 12 (8.33%)</p> <p>2</p> | <p>0 / 12 (0.00%)</p> <p>0</p> | <p>0 / 12 (0.00%)</p> <p>0</p> |
| <p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nausea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vomiting</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>1 / 12 (8.33%)</p> <p>1</p> <p>1 / 12 (8.33%)</p> <p>1</p> | <p>1 / 12 (8.33%)</p> <p>1</p> <p>3 / 12 (25.00%)</p> <p>3</p> <p>1 / 12 (8.33%)</p> <p>1</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>1 / 12 (8.33%)</p> <p>1</p> <p>0 / 12 (0.00%)</p> <p>0</p> |
| <p>Skin and subcutaneous tissue disorders</p> <p>Rash</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Hyperhidrosis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>1 / 12 (8.33%)</p> <p>1</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Arthralgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Back pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Limb discomfort</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Musculoskeletal stiffness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Myalgia</p> | <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0</p> | <p>2 / 12 (16.67%)</p> <p>2</p> <p>1 / 12 (8.33%)</p> <p>1</p> <p>1 / 12 (8.33%)</p> <p>1</p> <p>0 / 12 (0.00%)</p> <p>0</p> | <p>1 / 12 (8.33%)</p> <p>1</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>1 / 12 (8.33%)</p> <p>1</p> |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| Non-serious adverse events | Group D | Group E | |
|---|------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 12 (83.33%) | 11 / 12 (91.67%) | |
| Vascular disorders | | | |
| Pallor | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Chills | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 3 / 12 (25.00%) | |
| occurrences (all) | 1 | 3 | |
| Injection site erythema | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 2 / 12 (16.67%) | |
| occurrences (all) | 2 | 2 | |
| Injection site induration | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 3 / 12 (25.00%) | |
| occurrences (all) | 2 | 3 | |
| Injection site pain | | | |
| subjects affected / exposed | 8 / 12 (66.67%) | 7 / 12 (58.33%) | |
| occurrences (all) | 15 | 7 | |
| Injection site pruritus | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 3 / 12 (25.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Injection site swelling | | | |
| subjects affected / exposed | 2 / 12 (16.67%) | 3 / 12 (25.00%) | |
| occurrences (all) | 2 | 3 | |
| Pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Reproductive system and breast disorders | | | |
| Vulvovaginal pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Productive cough | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sinus pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Investigations | | | |

| | | | |
|--|--|---|--|
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| White blood cell count decreased subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 2 / 12 (16.67%) 3 | |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |
| Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Muscle strain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 5 / 12 (41.67%) 7 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 5 / 12 (41.67%) 6 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Blood and lymphatic system disorders Eosinophilia subjects affected / exposed occurrences (all) Anaemia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 1 / 12 (8.33%) 1 | |

| | | | |
|--|--|---|--|
| Ear and labyrinth disorders Excessive cerumen production subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Eye disorders Lacrimation increased subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 2 / 12 (16.67%) 2 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all) Hyperhidrosis subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Limb discomfort subjects affected / exposed occurrences (all) Musculoskeletal stiffness | 0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |

| | | | |
|--|----------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Myalgia subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 | 1 / 12 (8.33%) 1 | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|----------------|--|
| 31 July 2018 | Amendment 1.3- Primary reason for amendment was to adjust the safety stopping rules for participants who develop serious adverse reaction (SAR); Another change was including additional information for pregnancy test and contraception; added description of the circumstances in which a woman was considered of childbearing potential. |
| 21 August 2018 | Amendment 1.4- Primary reason for amendment was to change the Principal Investigator name and phone number; another change was in the volume of reconstitution for the lyophilized product (from 0.4 mL/dose to 0.5 mL/dose) and change in the injection volume (from 0.3 mL/dose to 0.4 mL/dose) |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported