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	v1
This version publication date	09 September 2021
First version publication date	09 September 2021

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 with Measles Virus-Chikungunya (MV-CHIK) lyophilized formulation, low dose on day 0 and day 28.

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): 5x10^4 ±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 with MV-CHIK liquid low dose frozen formulation on day 0 and day 28.

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): 1x10^5 ±0.5 log TCID50/dose.

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

Arm description:

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

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): 1x10^5 ±0.5 log TCID50/dose.

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

Arm description:

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

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): 1x10^6 ±0.5 log TCID50/dose.

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

Arm description:

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

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): 1x10^6 ±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 with Measles Virus-Chikungunya (MV-CHIK) lyophilized formulation, low dose on day 0 and day 28.	
Reporting group title	Group B: Two MV-CHIK Liquid Frozen Low Dose
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: Two MV-CHIK Liquid Low Dose SPS®
Reporting group description:	
Participants received two vaccinations with MV-CHIK liquid low dose Stabilizing and Protecting Solution (SPS®) formulation on day 0 and day 28.	
Reporting group title	Group D: Two MV-CHIK Liquid Frozen High Dose
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: One MV-CHIK Liquid Frozen High Dose/Placebo
Reporting group description:	
Participants received one vaccination with MV-CHIK liquid frozen high dose formulation on day 0 and placebo on day 28.	

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 with Measles Virus-Chikungunya (MV-CHIK) lyophilized formulation, low dose on day 0 and day 28.	
Reporting group title	Group B: Two MV-CHIK Liquid Frozen Low Dose
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: Two MV-CHIK Liquid Low Dose SPS®
Reporting group description:	
Participants received two vaccinations with MV-CHIK liquid low dose Stabilizing and Protecting Solution (SPS®) formulation on day 0 and day 28.	
Reporting group title	Group D: Two MV-CHIK Liquid Frozen High Dose
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: One MV-CHIK Liquid Frozen High Dose/Placebo
Reporting group description:	
Participants received one vaccination with MV-CHIK liquid frozen high dose formulation on day 0 and placebo on day 28.	

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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 1)	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 1)	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 1)	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 1)	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 1)	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 1)	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 1)	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 1)	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.	
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.	
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 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 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 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 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 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 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 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 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 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 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 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.	
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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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

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

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.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

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 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 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.

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.

Serious adverse events	Group B	Group A	Group D
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 E	Group C	
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 adverse events			

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

Non-serious adverse events	Group B	Group A	Group D
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 12 (91.67%)	10 / 12 (83.33%)	10 / 12 (83.33%)
Vascular disorders			
Pallor			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Influenza like illness			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Injection site erythema			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
Injection site induration			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Injection site pain			
subjects affected / exposed	3 / 12 (25.00%)	2 / 12 (16.67%)	8 / 12 (66.67%)
occurrences (all)	5	3	15
Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	3 / 12 (25.00%)
occurrences (all)	0	0	3
Injection site swelling			

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

increased			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
White blood cell count decreased			
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%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	2 / 12 (16.67%)
occurrences (all)	2	0	2
Headache			
subjects affected / exposed	5 / 12 (41.67%)	5 / 12 (41.67%)	5 / 12 (41.67%)
occurrences (all)	7	8	7
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
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
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	3 / 12 (25.00%)	1 / 12 (8.33%)	2 / 12 (16.67%)
occurrences (all)	3	1	2
Vomiting			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Limb discomfort			
subjects affected / exposed	1 / 12 (8.33%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

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

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

Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	2	
Injection site swelling			
subjects affected / exposed	3 / 12 (25.00%)	1 / 12 (8.33%)	
occurrences (all)	3	3	
Pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	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	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Oropharyngeal pain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
Productive cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Sinus pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Investigations			

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

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

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