



Clinical trial results:

A Randomized, Observer-blinded, Dose Response Phase 2 Trial to Assess the Safety and Immunogenicity of Two Different Dose Levels of a Live-attenuated Chikungunya Virus Vaccine (VLA1553) in Healthy Children Aged 1 to 11 Years

PIP #: P/0457/2021 and P/0501/2023

Summary

EudraCT number	2026-000022-41
Trial protocol	Outside EU/EEA
Global end of trial date	02 July 2025

Results information

Result version number	v1 (current)
This version publication date	03 September 2026
First version publication date	03 September 2026

Trial information

Trial identification

Sponsor protocol code	VLA1553-221
-----------------------	-------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06106581
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Valneva Austria GmbH
Sponsor organisation address	Campus Vienna Biocenter3, Vienna, Austria, 1030
Public contact	Study Director, Valneva Austria GmbH, 0043 1206200, office@valneva.com
Scientific contact	Study Director, Valneva Austria GmbH, 0043 1206200, office@valneva.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA/PE/0000265459
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	20 January 2026
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the tolerability of the full dose and half dose formulation of the live-attenuated CHIKV vaccine (VLA1553) following vaccination in healthy children aged 1 to 11 years after a single immunization.

Protection of trial subjects:

Number of trial visits and interventions was limited to the minimum required to generate the required safety and immunogenicity data. Participants were closely monitored for safety during the entire trial period. Participant diaries were distributed for the collection of safety information from the day of vaccination until the first 14 post-vaccination days. Memory Aids were distributed for the collection of safety information outside the first 14 post-vaccination days until trial end. An independent Data Safety Monitoring Board was established that continuously reviewed accruing safety information or ad-hoc safety data, as needed, to ensure participants' wellbeing.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 December 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Dominican Republic: 194
Country: Number of subjects enrolled	Honduras: 110
Worldwide total number of subjects	304
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	44

months)	
Children (2-11 years)	260
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited between 18-Dec-2023 and 17-Jul-2024 at two sites in the Dominican Republic and one site in Honduras.

Pre-assignment

Screening details:

In total, 391 participants were screened, 56 were screening failures. The reasons for screening failures were:

- failure to meet eligibility criteria 55 (98.2)
- physician decision 31 (55.4)
- withdrawal by participant 1 (1.8)
- Other 10 (17.9)

Period 1

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

Blinding implementation details:

In order to minimize/avoid bias, assignment into one of the trial arms was blinded for the participants and the site staff performing the safety assessments as well as the biostatistician (i.e. double-blind). Randomization was performed via the RTSM. At Day 1 (Visit 1, Day of vaccination) eligible participants were assigned to VLA1553 or control. Participants were allocated to trial arms according to the randomization code.

Arms

Are arms mutually exclusive?	Yes
Arm title	CHIKV vaccine Half Dose

Arm description:

CHIKV vaccine Half Dose formulation (target 3.7 log 10 TCID50 per 0.5 mL)

Arm type	Experimental
Investigational medicinal product name	CHIKV vaccine Half Dose
Investigational medicinal product code	VLA1553
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

CHIKV vaccine Half Dose formulation (target 3.7 log 10 TCID50 per 0.5 mL) - Lyophilisate for solution for injection

Arm title	CHIKV vaccine Full Dose
------------------	-------------------------

Arm description:

CHIKV vaccine Full Dose formulation (target 4.0 log 10 TCID50 per 0.5 mL)

Arm type	Experimental
Investigational medicinal product name	CHIKV vaccine Full Dose
Investigational medicinal product code	VLA1553
Other name	
Pharmaceutical forms	Solution for injection in vial
Routes of administration	Intramuscular use

Dosage and administration details:

CHIKV vaccine Half Dose formulation (target 4.0 log 10 TCID50 per 0.5 mL) - Lyophilisate for solution

Arm title	Nimenrix
Arm description:	
Nimenrix is a conjugate vaccine indicated for the active immunization of individuals from the age of 6 weeks against invasive meningococcal disease caused by <i>Neisseria meningitidis</i> groups A, C, W-135, and Y. Nimenrix is present as powder and solvent for solution for injection in pre-filled syringe. The reconstituted vaccine is a clear colourless solution. Nimenrix should be used in accordance with available official recommendations. Primary immunization in infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.	
Arm type	Active comparator
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Nimenrix is a conjugate vaccine indicated for the active immunization of individuals from the age of 6 weeks against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, C, W-135, and Y. Nimenrix is present as powder and solvent for solution for injection in pre-filled syringe. The reconstituted vaccine is a clear colourless solution. Nimenrix should be used in accordance with available official recommendations. Primary immunization in infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.

Number of subjects in period 1	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix
Started	119	124	61
Completed	115	122	60
Not completed	4	2	1
Consent withdrawn by subject	1	-	1
Physician decision	1	-	-
n/a	-	1	-
Lost to follow-up	2	1	-

Baseline characteristics

Reporting groups

Reporting group title	CHIKV vaccine Half Dose
Reporting group description:	
CHIKV vaccine Half Dose formulation (target 3.7 log ₁₀ TCID ₅₀ per 0.5 mL)	
Reporting group title	CHIKV vaccine Full Dose
Reporting group description:	
CHIKV vaccine Full Dose formulation (target 4.0 log ₁₀ TCID ₅₀ per 0.5 mL)	
Reporting group title	Nimenrix
Reporting group description:	
Nimenrix is a conjugate vaccine indicated for the active immunization of individuals from the age of 6 weeks against invasive meningococcal disease caused by <i>Neisseria meningitidis</i> groups A, C, W-135, and Y. Nimenrix is present as powder and solvent for solution for injection in pre-filled syringe. The reconstituted vaccine is a clear colourless solution. Nimenrix should be used in accordance with available official recommendations. Primary immunization in infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.	

Reporting group values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix
Number of subjects	119	124	61
Age categorical			
Units: Subjects			
1 - 2 Years	39	41	20
3 - 6 Years	40	40	20
7 - 11 Years	40	43	21
Age continuous			
Units: years			
geometric mean	5.0	5.0	5.1
standard deviation	± 3.05	± 3.05	± 3.37
Gender categorical			
Units: Subjects			
Female	52	65	29
Male	67	59	32

Reporting group values	Total		
Number of subjects	304		
Age categorical			
Units: Subjects			
1 - 2 Years	100		
3 - 6 Years	100		
7 - 11 Years	104		
Age continuous			
Units: years			
geometric mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	146		
Male	158		

Subject analysis sets

Subject analysis set title	Safety
Subject analysis set type	Safety analysis

Subject analysis set description:

The safety analysis population contains all participants who entered into the trial and received one vaccination.

Subject analysis set title	Per-Protocol
Subject analysis set type	Per protocol

Subject analysis set description:

The per protocol analysis population (PP) contains all seronegative participants of the Immunogenicity Analysis Population (The IMM includes all vaccinated participants who have evaluable μ PRNT antibody titer results at baseline (Visit 1/ Day 1) who have no major protocol violations that could impact immune response.

Reporting group values	Safety	Per-Protocol	
Number of subjects	304	275	
Age categorical Units: Subjects			
1 - 2 Years	100	98	
3 - 6 Years	100	99	
7 - 11 Years	104	78	
Age continuous Units: years			
geometric mean	5.0	4.6	
standard deviation	± 3.11	± 2.83	
Gender categorical Units: Subjects			
Female	146	134	
Male	158	141	

End points

End points reporting groups

Reporting group title	CHIKV vaccine Half Dose
Reporting group description: CHIKV vaccine Half Dose formulation (target 3.7 log ₁₀ TCID ₅₀ per 0.5 mL)	
Reporting group title	CHIKV vaccine Full Dose
Reporting group description: CHIKV vaccine Full Dose formulation (target 4.0 log ₁₀ TCID ₅₀ per 0.5 mL)	
Reporting group title	Nimenrix
Reporting group description: Nimenrix is a conjugate vaccine indicated for the active immunization of individuals from the age of 6 weeks against invasive meningococcal disease caused by <i>Neisseria meningitidis</i> groups A, C, W-135, and Y. Nimenrix is present as powder and solvent for solution for injection in pre-filled syringe. The reconstituted vaccine is a clear colourless solution. Nimenrix should be used in accordance with available official recommendations. Primary immunization in infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.	
Subject analysis set title	Safety
Subject analysis set type	Safety analysis
Subject analysis set description: The safety analysis population contains all participants who entered into the trial and received one vaccination.	
Subject analysis set title	Per-Protocol
Subject analysis set type	Per protocol
Subject analysis set description: The per protocol analysis population (PP) contains all seronegative participants of the Immunogenicity Analysis Population (The IMM includes all vaccinated participants who have evaluable μ PRNT antibody titer results at baseline (Visit 1/ Day 1) who have no major protocol violations that could impact immune response.	

Primary: 1. Number of Participants with solicited injection site reactions

End point title	1. Number of Participants with solicited injection site
End point description:	
End point type	Primary
End point timeframe: within 14 days post-vaccination	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: safety analysis was chosen

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
7 - 11 Years	12	8	7	27
3 - 6 Years	6	7	0	13
1 - 2 Years	3	1	1	5

Statistical analyses

No statistical analyses for this end point

Primary: 2. Severity of solicited injection site reactions

End point title 2. Severity of solicited injection site reactions^[2]

End point description:

Safety Population

End point type Primary

End point timeframe:

within 14 days post-vaccination

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: safety analysis was chosen

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Grade 4: 7 - 11 Years	0	0	0	0
Grade 3: 7 - 11 Years	0	0	0	0
Grade 2: 7 - 11 Years	5	1	2	8
Grade 1: 7 - 11 Years	9	7	6	24
Grade 4: 3 - 6 Years	0	0	0	0
Grade 3: 3 - 6 Years	0	0	0	0
Grade 2: 3 - 6 Years	0	0	0	0
Grade 1: 3 - 6 Years	6	7	0	13
Grade 4: 1 - 2 Years	0	0	0	0
Grade 3: 1 - 2 Years	0	0	0	0
Grade 2: 1 - 2 Years	0	0	0	0
Grade 1: 1 - 2 Years	3	1	1	5

Statistical analyses

No statistical analyses for this end point

Primary: 3. Number of Participants with solicited systemic reactions

End point title 3. Number of Participants with solicited systemic reactions^[3]

End point description:

End point type	Primary
End point timeframe:	
within 14 days post-vaccination	
Notes:	
[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: safety analysis was chosen	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
7 - 11 years	11	17	3	31
3 - 6 years	10	10	4	24
1 - 2 years	9	15	3	27

Statistical analyses

No statistical analyses for this end point

Primary: 4. Severity of solicited systemic reactions

End point title	4. Severity of solicited systemic reactions ^[4]
End point description:	

End point type	Primary
End point timeframe:	
within 14 days post-vaccination	
Notes:	
[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: safety analysis was chosen	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Grade 4: 7 - 11 Years	0	0	0	0
Grade 3: 7 - 11 Years	0	0	0	0
Grade 2: 7 - 11 Years	8	3	0	3
Grade 1: 7 - 11 Years	6	15	3	24
Grade 4: 3 - 6 Years	0	0	0	0
Grade 3: 3 - 6 Years	0	3	0	3
Grade 2: 3 - 6 Years	0	2	3	5
Grade 1: 3 - 6 Years	10	9	1	20
Grade 4: 1 - 2 Years	1	0	0	1
Grade 3: 1 - 2 Years	1	1	0	2
Grade 2: 1 - 2 Years	1	3	1	5

Grade 1: 1 - 2 Years	7	13	2	22
----------------------	---	----	---	----

Statistical analyses

No statistical analyses for this end point

Secondary: 5. Number of Participants with any adverse event (AE)

End point title	5. Number of Participants with any adverse event (AE)
End point description:	
Safety Population	
End point type	Secondary
End point timeframe:	
within 28 days post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
7 - 11 Years	22	23	11	56
3 - 6 Years	20	16	6	42
1 - 2 Years	16	20	8	44

Statistical analyses

No statistical analyses for this end point

Secondary: 6. Severity of any adverse event (AE)

End point title	6. Severity of any adverse event (AE)
End point description:	
In the Outcome measure "Severity of any AE", subjects may be represented in more than one AE category. Therefore, the total number of subjects with any AE may be lower than the sum of the numbers of subjects in the individual AE categories (solicited / unsolicited AE).	
End point type	Secondary
End point timeframe:	
within 28 days post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
any solicited AE: 7 - 11 Years	17	20	9	46
Solicited AE Grade 4: 7 - 11 Years	0	0	0	0
solicited AE Grade 3: 7 - 11 Years	0	0	0	0
solicited AE Grade 2: 7 - 11 Years	11	4	2	17
solicited AE Grade 1: 7 - 11 Years	6	16	7	29
any unsolicited AE: 7 - 11 Years	10	13	6	29
unsolicited AE Grade 4: 7 - 11 Years	0	0	0	0
unsolicited AE Grade 3: 7 - 11 Years	1	0	0	1
unsolicited AE Grade 2: 7 - 11 Years	2	0	1	3
unsolicited AE Grade 1: 7 - 11 Years	7	13	5	25
any solicited AE: 3 - 6 Years	14	12	4	30
Solicited AE Grade 4: 3 - 6 Years	0	0	0	0
Solicited AE Grade 3: 3 - 6 Years	0	3	0	3
Solicited AE Grade 2: 3 - 6 Years	0	2	3	5
Solicited AE Grade 1: 3 - 6 Years	14	7	1	22
any unsolicited AE: 3 - 6 Years	12	11	5	27
unsolicited AE Grade 4: 3 - 6 Years	0	0	0	0
unsolicited AE Grade 3: 3 - 6 Years	0	0	0	0
unsolicited AE Grade 2: 3 - 6 Years	1	2	0	3
unsolicited AE Grade 1: 3 - 6 Years	11	9	5	25
any solicited AE: 1 - 2 Years	10	15	3	28
Solicited AE Grade 4: 1 - 2 Years	1	0	0	1
Solicited AE Grade 3: 1 - 2 Years	1	1	0	2
Solicited AE Grade 2: 1 - 2 Years	1	3	1	5
Solicited AE Grade 1: 1 - 2 Years	7	11	2	20
any unsolicited AE: 1 - 2 Years	12	13	6	31
unsolicited AE Grade 4: 1 - 2 Years	0	0	0	0
unsolicited AE Grade 3: 1 - 2 Years	1	0	0	1
unsolicited AE Grade 2: 1 - 2 Years	0	0	0	0
unsolicited AE Grade 1: 1 - 2 Years	11	13	6	30

Statistical analyses

No statistical analyses for this end point

Secondary: 7. Number of Participants with of unsolicited AE

End point title	7. Number of Participants with of unsolicited AE
End point description:	
Safety Population	
End point type	Secondary
End point timeframe:	
until Month 6 (Day 180) and Month 12 (Day 365) post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Month 6/Day 180: 7 - 11 Years	25	25	11	61
Month 12/Day 365: 7 - 11 Years	25	31	12	68
Month 6/Day 180: 3 - 6 Years	27	20	13	60
Month 12/Day 365: 3 - 6 Years	30	24	16	70
Month 6/Day 180: 1 - 2 Years	27	28	14	69
Month 12/Day 365: 1 - 2 Year	29	33	17	79

Statistical analyses

No statistical analyses for this end point

Secondary: 8. Severity of unsolicited AE

End point title	8. Severity of unsolicited AE
End point description:	
Safety Population	
End point type	Secondary
End point timeframe:	
until Month 6 (Day 180) and Month 12 (Day 365) post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Month 6 Grade 4: 7 - 11 Years	0	0	0	0
Month 6 Grade 3: 7 - 11 Years	1	2	0	3
Month 6 Grade 2: 7 - 11 Years	8	4	3	15
Month 6 Grade 1: 7 - 11 Years	16	19	8	43
Month 12 Grade 4: 7 - 11 Years	0	0	0	0
Month 12 Grade 3: 7 - 11 Years	1	4	1	6
Month 12 Grade 2: 7 - 11 Years	10	5	4	19
Month 12 Grade 1: 7 - 11 Years	14	22	7	43
Month 6 Grade 4: 3 - 6 Years	0	0	0	0
Month 6 Grade 3: 3 - 6 Years	1	0	0	1
Month 6 Grade 2: 3 - 6 Years	8	4	2	14
Month 6 Grade 1: 3 - 6 Years	18	16	11	45

Month 12 Grade 4: 3 - 6 Years	0	0	0	0
Month 12 Grade 3: 3 - 6 Years	2	0	0	2
Month 12 Grade 2: 3 - 6 Years	9	8	5	22
Month 12 Grade 1: 3 - 6 Years	19	16	11	46
Month 6 Grade 4: 1 - 2 Years	0	0	0	0
Month 6 Grade 3: 1 - 2 Years	3	2	0	5
Month 6 Grade 2: 1 - 2 Years	8	7	4	19
Month 6 Grade 1: 1 - 2 Years	16	19	10	45
Month 12 Grade 4: 1 - 2 Years	0	0	1	1
Month 12 Grade 3: 1 - 2 Years	3	2	0	5
Month 12 Grade 2: 1 - 2 Years	11	16	6	33
Month 12 Grade 1: 1 - 2 Years	15	15	10	40

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Number of Participants with any serious adverse event (SAE)

End point title	9. Number of Participants with any serious adverse event (SAE)
End point description:	
Safety Population	
End point type	Secondary
End point timeframe:	
until Month 6 (Day 180) and Month 12 (Day 365) post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Month 6/Day 180: 7 - 11 Years	1	0	0	1
Month 12/Day 365: 7 - 11 Years	1	2	0	3
Month 6/Day 180: 3 - 6 Years	0	0	0	0
Month 12/Day 365: 3 - 6 Years	1	0	0	1
Month 6/Day 180: 1 - 2 Years	0	1	0	1
Month 12/Day 365: 1 - 2 Years	0	2	1	3

Statistical analyses

No statistical analyses for this end point

Secondary: 10. Number of Participants with any early onset adverse event of special interest (AESI)

End point title	10. Number of Participants with any early onset adverse event of special interest (AESI)
End point description: Early onset AESI were defined as: 1. Fever (≥ 38.0 °c / 100.4 °f,) AND 2. symptoms suggesting acute (poly)arthralgia/arthritis, myalgia, neurological symptoms (e.g., for meningoencephalitis, acute encephalitis, headache, seizures), back pain, lymphadenopathy, cardiac or ocular symptoms (e.g., for uveitis and retinitis); OR one or more of the following signs and symptoms: macular to maculopapular rash (sometimes with cutaneous pruritus [foot plant]), pigmentary changes, bullous rash/ skin blistering, purpura, ecchymosis and 3. Onset of symptoms 2 to 21 days after vaccination AND 4. Duration of event ≥ 3 days.	
End point type	Secondary
End point timeframe: 2 to 21 days post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)	3	0	0	3

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Severity of any early onset adverse event of special interest (AESI)

End point title	11. Severity of any early onset adverse event of special interest (AESI)
End point description: Safety Population	
End point type	Secondary
End point timeframe: 2 to 21 days post-vaccination	

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Grade 4	0	0	0	0
Grade 3	0	0	0	0
Grade 2	2	0	0	2

Grade 1	1	0	0	1
---------	---	---	---	---

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Number of Participants with any late onset adverse event of special interest (AESI)

End point title	12. Number of Participants with any late onset adverse event of special interest (AESI)
-----------------	---

End point description:

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

End point timeframe:

Starting 22 days post-vaccination until end of trial, 12 months post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)	2	0	0	2

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Severity of any late onset adverse event of special interest (AESI)

End point title	13. Severity of any late onset adverse event of special interest (AESI)
-----------------	---

End point description:

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

End point timeframe:

Starting 22 days post-vaccination until end of trial, 12 months post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	Safety
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	119	124	61	304
Units: participants				
number (not applicable)				
Grade 4	0	0	0	0
Grade 3	0	0	0	0
Grade 2	1	0	0	1
Grade 1	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Assessment of viremia

End point title	14. Assessment of viremia
End point description:	Viremia subset of the Safety Analysis Population including 124 participants.
End point type	Secondary
End point timeframe:	on Days 1, 4, 8 and 15 and beyond as applicable

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	53	21	
Units: participants				
number (not applicable)				
Visit 1/Day 1: Quantifiable	0	0	0	
Visit 1/Day 1: Below LLOQ	0	0	0	
Visit 2/Day 4: Quantifiable	12	23	0	
Visit 2/Day 4: Below LLOQ	6	10	0	
Visit 3/Day 8: Quantifiable	10	8	0	
Visit 3/Day 8: Below LLOQ	6	5	0	
Visit 4/Day 15: Quantifiable	1	0	0	
Visit 4/Day 15: Below LLOQ	0	0	0	
Visit 5/Day 29: Quantifiable	0	0	0	
Visit 5/Day 29: Below LLOQ	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Immune response in baseline seronegative participants as measured by CHIKV-specific neutralizing antibody titers

End point title	15. Immune response in baseline seronegative participants as measured by CHIKV-specific neutralizing antibody titers
-----------------	--

End point description:

Immune Response provided by Geometric Mean Titers (GMTs) in Baseline Seronegative Participants pooled by Trial Arm up to 12 months post vaccination.

Immunogenicity Population - seronegative at baseline (μ PRNT50 $\leq$ 40)

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

End point timeframe:

on Day 1, Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	116	53	
Units: titer				
geometric mean (confidence interval 95%)				
Visit 1/Day 1	10.1 (9.9 to 10.3)	10.0 (10.0 to 10.0)	10.3 (9.9 to 10.7)	
Visit 4/Day 15	1046.1 (726.6 to 1506.0)	1949.9 (1513.7 to 2511.8)	10.2 (9.8 to 10.7)	
Visit 5/Day 29	1845.4 (1300.3 to 2618.8)	2860.6 (2267.8 to 3608.3)	10.3 (9.9 to 10.8)	
Visit 6/Day 85	630.8 (465.8 to 854.4)	1031.5 (830.6 to 1281.0)	10.0 (10.0 to 10.0)	
Visit 7/Day 180	514.2 (383.2 to 690.0)	813.7 (658.5 to 1005.4)	10.0 (10.0 to 10.0)	
Visit 8/Day 365	798.7 (573.4 to 1112.5)	1355.7 (1071.5 to 1715.2)	10.5 (9.9 to 11.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: 16. Immune Response as measured by CHIKV-specific neutralizing antibody titers by age group and trial arm.

End point title	16. Immune Response as measured by CHIKV-specific neutralizing antibody titers by age group and trial arm.
-----------------	--

End point description:

Immune Response provided by Geometric Mean Titers (GMTs) by Visit, by Age Group and Trial Arm up to 12 months post vaccination. (Per-Protocol Analysis)

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

End point timeframe:

on Day 1, Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: titer				
geometric mean (confidence interval 95%)				
Visit 1/Day 1: 7 - 11 Years	10.0 (10.0 to 10.0)	10.0 (10.0 to 10.0)	10.7 (9.3 to 12.3)	
Visit 4/Day 15: 7 - 11 Years	836.0 (443.2 to 1576.7)	2214.5 (1716.3 to 2857.2)	10.0 (10.0 to 10.0)	
Visit 5/Day 29: 7 - 11 Years	1979.1 (941.9 to 4158.4)	3443.6 (2957.0 to 4010.3)	10.0 (10.0 to 10.0)	
Visit 6/Day 85: 7 - 11 Years	634.5 (347.7 to 1157.7)	1240.8 (1003.9 to 1533.6)	10.0 (10.0 to 10.0)	
Visit 7/Day 180: 7 - 11 Years	573.8 (315.9 to 1042.1)	835.4 (648.3 to 1076.7)	10.0 (10.0 to 10.0)	
Visit 8/Day 365: 7 - 11 Years	693.3 (376.4 to 1277.2)	1451.0 (1102.4 to 1909.9)	10.7 (9.3 to 12.3)	
Visit 1/Day 1: 3 - 6 Years	10.3 (9.7 to 10.8)	10.0 (10.0 to 10.0)	10.0 (10.0 to 10.0)	
Visit 4/Day 15: 3 - 6 Years	1437.4 (836.1 to 2471.1)	2275.4 (1518.3 to 3410.3)	10.0 (10.0 to 10.0)	
Visit 5/Day 29: 3 - 6 Years	2170.2 (1304.9 to 3609.2)	3134.8 (2108.4 to 4660.7)	10.0 (10.0 to 10.0)	
Visit 6/Day 85: 3 - 6 Years	763.4 (497.7 to 1170.9)	1073.7 (763.8 to 1509.2)	10.0 (10.0 to 10.0)	
Visit 7/Day 180: 3 - 6 Years	468.0 (313.2 to 699.4)	872.4 (635.4 to 1197.8)	10.0 (10.0 to 10.0)	
Visit 8/Day 365: 3 - 6 Years	858.6 (524.5 to 1405.4)	1382.2 (975.0 to 1959.5)	10.0 (10.0 to 10.0)	
Visit 1/Day 1: 1 - 2 Years	10.0 (10.0 to 10.0)	10.0 (10.0 to 10.0)	10.4 (9.6 to 11.1)	
Visit 4/Day 15: 1 - 2 Years	960.3 (462.7 to 1993.1)	1474.5 (808.7 to 2688.8)	10.7 (9.3 to 12.3)	
Visit 5/Day 29: 1 - 2 Years	1439.2 (730.0 to 2837.1)	2161.7 (1235.0 to 3783.7)	11.0 (9.6 to 12.5)	
Visit 6/Day 85: 1 - 2 Years	517.5 (277.9 to 963.8)	831.1 (500.1 to 1381.1)	10.0 (10.0 to 10.0)	
Visit 7/Day 180: 1 - 2 Years	506.0 (272.4 to 940.0)	820.1 (517.8 to 1298.9)	10.0 (10.0 to 10.0)	
Visit 8/Day 365: 1 - 2 Years	814.0 (400.4 to 1654.7)	1242.6 (703.3 to 2195.8)	10.8 (9.6 to 12.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: 17. Immune Response Measured by CHIKV-specific Neutralizing Antibody Titers pooled by Dose

End point title	17. Immune Response Measured by CHIKV-specific Neutralizing Antibody Titers pooled by Dose
-----------------	--

End point description:

Immune Response provided by Geometric Mean Titers (GMTs) by Visit, pooled by Trial Arm up to 12 months post vaccination. (Per-Protocol Analysis)

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

End point timeframe:

on Day 1, Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: titer				
geometric mean (confidence interval 95%)				
Visit 1/Day 1	10.1 (9.9 to 10.3)	10.0 (10.0 to 10.0)	10.3 (9.9 to 10.7)	
Visit 4/Day 15	1073.6 (748.1 to 1540.7)	1944.8 (1506.5 to 2510.8)	10.2 (9.8 to 10.8)	
Visit 5/Day 29	1829.3 (1280.8 to 2612.8)	2843.6 (2247.1 to 3598.5)	10.3 (9.9 to 10.8)	
Visit 6/Day 85	631.4 (463.5 to 860.2)	1025.9 (824.8 to 1276.2)	10.0 (10.0 to 10.0)	
Visit 7/Day 180	508.5 (377.1 to 685.8)	842.5 (689.1 to 1030.1)	10.0 (10.0 to 10.0)	
Visit 8/Day 365	794.5 (566.8 to 1113.7)	1353.4 (1067.5 to 1715.8)	10.5 (9.9 to 11.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Percentage of Participants seronegative at baseline with seroconversion as compared to baseline

End point title	18. Percentage of Participants seronegative at baseline with seroconversion as compared to baseline
-----------------	---

End point description:

Percentage of participants seronegative at baseline with Seroconversion (defined as >4-fold titer change compared to baseline) by Visit Pooled by Trial Arm (µRPNT Baseline Seronegative Immunogenicity Analysis Population)

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	116	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15	88.0	95.7	0.0	
Visit 5/Day 29	89.89	95.7	0.0	
Visit 6/Day 85	89.5	95.7	0.0	
Visit 7/Day 180	89.7	95.7	0.0	
Visit 8/Day 365	89.6	95.7	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percentage of participants seropositive at baseline with seroconversion as compared to baseline

End point title	19. Percentage of participants seropositive at baseline with seroconversion as compared to baseline
-----------------	---

End point description:

Percentage of participants seropositive at baseline with Seroconversion (defined as >4-fold titer change compared to baseline) by Visit Pooled by Trial Arm. (µRPNT Baseline Seropositive Immunogenicity Analysis Population)

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	7	8	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15	0.0	0.0	0.0	
Visit 5/Day 29	0.0	0.0	0.0	
Visit 6/Day 85	0.0	0.0	0.0	
Visit 7/Day 180	0.0	0.0	12.5	
Visit 8/Day 365	0.0	0.0	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: 20. Percentage of participants with seroconversion as compared to baseline stratified by age stratum

End point title	20. Percentage of participants with seroconversion as compared to baseline stratified by age stratum
-----------------	--

End point description:

Percentage of participants with Seroconversion (defined as >4-fold titer change compared to baseline) by Visit by Age Group and Trial Arm. (Per-Protocol Analysis Population)

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15: 7 - 11 Years	89.7	100.0	0.0	
Visit 5/Day 29: 7 - 11 Years	89.7	100.0	0.0	
Visit 6/Day 85: 7 - 11 Years	89.7	100.0	0.0	
Visit 7/Day 180: 7 - 11 Years	89.7	100.0	0.0	
Visit 8/Day 365: 7 - 11 Years	89.7	100.0	0.0	
Visit 4/Day 15: 3 - 6 Years	92.3	97.4	0.0	
Visit 5/Day 29: 3 - 6 Years	92.5	97.4	0.0	
Visit 6/Day 85: 3 - 6 Years	94.6	97.4	0.0	
Visit 7/Day 180: 3 - 6 Years	95.0	97.4	0.0	
Visit 8/Day 365: 3 - 6 Years	92.5	97.4	0.0	
Visit 4/Day 15: 1 - 2 Years	83.8	89.7	0.0	
Visit 5/Day 29: 1 - 2 Years	86.8	89.7	0.0	
Visit 6/Day 85: 1 - 2 Years	83.3	90.0	0.0	
Visit 7/Day 180: 1 - 2 Years	83.3	92.3	0.0	
Visit 8/Day 365: 1 - 2 Years	85.7	89.7	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: 21. Percentage of Participants With Seroconversion as Compared to Baseline by dose

End point title	21. Percentage of Participants With Seroconversion as Compared to Baseline by dose
-----------------	--

End point description:

Percentage of participants with Seroconversion (defined as >4-fold titer change compared to baseline) by Visit Pooled by Trial Arm (Per-Protocol Analysis Population)

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15	88.6	95.6	0.0	
Visit 5/Day 29	89.7	95.6	0.0	
Visit 6/Day 85	89.2	95.6	0.0	
Visit 7/Day 180	89.5	96.5	0.0	
Visit 8/Day 365	89.4	95.6	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: 22. Percentage of participants seronegative at baseline with a seroresponse (defined as PRNT50 $\geq$ 150 for baseline negative participants) by dose

End point title	22. Percentage of participants seronegative at baseline with a seroresponse (defined as PRNT50 $\geq$ 150 for baseline negative participants) by dose
-----------------	---

End point description:

Percentage of Participants with Seroresponse for CHIKV-Specific Neutralizing Antibody Titers (defined as PRNT50 $\geq$ 150) by Visit Pooled by Trial Arm. (μ RPNT Baseline Seronegative Immunogenicity Analysis Population)

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

End point timeframe:

on Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	116	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15	87.0	95.7	0.0	
Visit 5/Day 29	89.0	95.7	0.0	
Visit 6/Day 85	87.6	95.7	0.0	
Visit 7/Day 180	88.8	95.7	0.0	
Visit 8/Day 365	86.8	94.8	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: 23. Percentage of participants with a seroresponse stratified by age stratum

End point title	23. Percentage of participants with a seroresponse stratified by age stratum
-----------------	--

End point description:

Percentage of Participants with Seroresponse for CHIKV-Specific Neutralizing Antibody Titers (defined as PRNT50 $\geq$ 150) by Visit by Age Group and Trial Arm. Per-Protocol Analysis Population

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

End point timeframe:

on Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15: 7 - 11 Years	89.66	100.00	0	
Visit 5/Day 29: 7 - 11 Years	89.66	100.0	0	
Visit 6/Day 85: 7 - 11 Years	89.66	100.00	0	
Visit 7/Day 180: 7 - 11 Years	89.66	100.00	0	
Visit 8/Day 365: 7 - 11 Years	89.66	97.22	0	
Visit 4/Day 15: 3 - 6 Years	92.31	97.44	0	
Visit 5/Day 29: 3 - 6 Years	92.50	97.44	0	
Visit 6/Day 85: 3 - 6 Years	91.89	97.44	0	
Visit 7/Day 180: 3 - 6 Years	92.50	97.44	0	
Visit 8/Day 365: 3 - 6 Years	90.00	97.44	0	
Visit 4/Day 15: 1 - 2 Years	81.08	89.74	0	
Visit 5/Day 29: 1 - 2 Years	84.21	89.74	0	
Visit 6/Day 85: 1 - 2 Years	83.33	90.00	0	
Visit 7/Day 180: 1 - 2 Years	83.33	92.31	0	
Visit 8/Day 365: 1 - 2 Years	80.00	89.74	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 24. Percentage of participants with a seroresponse stratified by dose

End point title	24. Percentage of participants with a seroresponse stratified by dose
-----------------	---

End point description:

Percentage of Participants with Seroresponse for CHIKV-Specific Neutralizing Antibody Titers (defined as PRNT50 $\geq$ 150) by Visit Pooled by Trial Arm. (Per-Protocol Analysis Population)

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

End point timeframe:

on Day 15, Day 29, Day 85, Day 180 and Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15	87.62	95.61	0	
Visit 5/Day 29	88.79	95.61	0	
Visit 6/Day 85	88.24	95.61	0	
Visit 7/Day 180	88.57	96.49	0	
Visit 8/Day 365	86.54	94.74	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 25. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline in participants seronegative at baseline

End point title	25. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline in participants seronegative at baseline
-----------------	---

End point description:

at Days 15, 29, 85, 180 and at Month 12 post-vaccination

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

End point timeframe:

Fold Change for CHIKV-Specific Neutralizing Antibody Titers in seronegative Participants by Visit Pooled by Trial Arm. (μ RPNT Baseline Seronegative Immunogenicity Analysis Population)

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	116	53	
Units: fold change				
geometric mean (confidence interval 95%)				

Visit 4/Day 15	103.6 (71.9 to 149.3)	195.0 (151.4 to 251.2)	1.0 (0.9 to 1.1)	
Visit 5/Day 29	182.8 (128.7 to 259.7)	286.1 (226.8 to 360.8)	1.0 (0.9 to 1.1)	
Visit 6/Day 85	62.5 (46.1 to 84.6)	103.1 (83.1 to 128.1)	1.0 (0.9 to 1.0)	
Visit 7/Day 180	50.9 (37.9 to 68.4)	81.4 (65.9 to 100.5)	1.0 (0.9 to 1.0)	
Visit 8/Day 365	79.1 (56.7 to 110.3)	135.6 (107.2 to 171.5)	1.0 (0.9 to 1.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: 26. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline in seropositive participants

End point title	26. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline in seropositive participants
End point description:	Fold Change for CHIKV-Specific Neutralizing Antibody Titers in seropositive Participants by Visit Pooled by Trial Arm.
End point type	Secondary
End point timeframe:	at Days 15, 29, 85, 180 and at Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	24	24	
Units: fold change				
geometric mean (confidence interval 95%)				
Visit 4/Day 15	0.9 (0.7 to 1.1)	1.4 (0.8 to 2.5)	1.1 (0.6 to 2.2)	
Visit 5/Day 29	0.8 (0.6 to 1.1)	1.9 (1.4 to 2.7)	1.2 (0.9 to 1.8)	
Visit 6/Day 85	0.8 (0.6 to 1.2)	1.9 (1.4 to 2.6)	1.4 (0.9 to 2.2)	
Visit 7/Day 180	1.2 (0.8 to 1.8)	1.1 (0.7 to 1.6)	1.2 (0.6 to 2.1)	
Visit 8/Day 365	0.9 (0.6 to 1.3)	1.2 (0.6 to 2.4)	1.4 (0.8 to 2.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: 27. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline stratified by age stratum

End point title	27. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline stratified by age stratum
-----------------	--

End point description:

Fold Change for CHIKV-Specific Neutralizing Antibody Titers by Visit by Age Group and Trial Arm.

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

End point timeframe:

at Days 15, 29, 85, 180 and at Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: fold change				
geometric mean (confidence interval 95%)				
Visit 4/Day 15: 7 - 11 Years	83.6 (44.3 to 157.7)	221.4 (17.6 to 285.7)	0.9 (0.8 to 1.1)	
Visit 5/Day 29: 7 - 11 Years	197.9 (94.2 to 415.8)	344.4 (295.7 to 401.0)	0.9 (0.8 to 1.1)	
Visit 6/Day 85: 7 - 11 Years	63.4 (34.8 to 115.8)	124.1 (100.4 to 153.4)	0.9 (0.8 to 1.1)	
Visit 7/Day 180: 7 - 11 Years	57.4 (31.6 to 104.2)	83.5 (64.8 to 107.7)	0.9 (0.8 to 1.1)	
Visit 8/Day 365: 7 - 11 Years	69.3 (37.6 to 127.7)	145.1 (110.2 to 191.0)	1.0 (0.8 to 1.2)	
Visit 4/Day 15: 3 - 6 Years	140.0 (80.9 to 242.2)	227.5 (151.8 to 341.0)	1.0 (1.0 to 1.0)	
Visit 5/Day 29: 3 - 6 Years	211.5 (126.3 to 354.2)	313.5 (210.8 to 466.1)	1.0 (1.0 to 1.0)	
Visit 6/Day 85: 3 - 6 Years	74.2 (48.3 to 114.2)	107.4 (76.4 to 150.9)	1.0 (1.0 to 1.0)	
Visit 7/Day 180: 3 - 6 Years	45.6 (30.4 to 68.4)	87.2 (63.5 to 119.8)	1.0 (1.0 to 1.0)	
Visit 8/Day 365: 3 - 6 Years	83.7 (50.8 to 137.9)	138.2 (97.5 to 195.9)	1.0 (1.0 to 1.0)	
Visit 4/Day 15: 1 - 2 Years	96.0 (46.3 to 199.3)	147.5 (80.9 to 268.9)	1.0 (0.9 to 1.2)	
Visit 5/Day 29: 1 - 2 Years	143.9 (73.0 to 283.7)	216.2 (123.5 to 378.4)	1.1 (0.9 to 1.2)	
Visit 6/Day 85: 1 - 2 Years	51.7 (27.8 to 96.4)	83.1 (50.0 to 138.1)	1.0 (0.9 to 1.0)	
Visit 7/Day 180: 1 - 2 Years	50.6 (27.2 to 94.0)	82.0 (51.8 to 129.9)	1.0 (0.9 to 1.0)	
Visit 8/Day 365: 1 - 2 Years	81.4 (40.0 to 165.5)	124.3 (70.3 to 219.6)	1.0 (0.9 to 1.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: 28. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline stratified by dose

End point title	28. Fold change of CHIKV-specific neutralizing antibody titers as compared to baseline stratified by dose
-----------------	---

End point description:

Fold Change for CHIKV-Specific Neutralizing Antibody Titers by Visit Pooled by Trial Arm.

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

End point timeframe:

at Days 15, 29, 85, 180 and at Month 12 post-vaccination

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: fold change				
geometric mean (confidence interval 95%)				
Visit 4/Day 15	106.3 (74.0 to 152.7)	194.5 (150.6 to 251.1)	1.0 (0.9 to 1.1)	
Visit 5/Day 29	181.2 (126.7 to 259.1)	284.4 (224.7 to 359.9)	1.0 (0.9 to 1.1)	
Visit 6/Day 85	62.5 (45.9 to 85.2)	102.6 (82.5 to 127.6)	1.0 (0.9 to 1.0)	
Visit 7/Day 180	50.4 (37.3 to 68.0)	84.3 (68.9 to 103.0)	1.0 (0.9 to 1.0)	
Visit 8/Day 365	78.7 (56.0 to 110.4)	135.3 (106.7 to 171.6)	1.0 (0.9 to 1.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: 29. Percentage of participants seronegative at baseline reaching an at least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific neutralizing antibody titers compared to baseline

End point title	29. Percentage of participants seronegative at baseline reaching an at least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific neutralizing antibody titers compared to baseline
-----------------	--

End point description:

Percentage of Participants Reaching a 4-/8-/16-/64-Fold Change in Titers by Visit Pooled by Trial Arm.

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	116	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15: 4-fold change	87.96	95.65	0	
Visit 4/Day 15: 8-fold change	87.96	95.65	0	
Visit 4/Day 15: 16-fold change	87.04	95.65	0	
Visit 4/Day 15: 64-fold change	76.85	89.57	0	
Visit 5/Day 29: 4-fold change	89.91	95.69	0	
Visit 5/Day 29: 8-fold change	88.99	95.69	0	
Visit 5/Day 29: 16-fold change	88.99	95.69	0	
Visit 5/Day 29: 64-fold change	87.16	95.69	0	
Visit 6/Day 85: 4-fold change	89.52	95.65	0	
Visit 6/Day 85: 8-fold change	89.52	95.65	0	
Visit 6/Day 85: 16-fold change	87.62	95.65	0	
Visit 6/Day 85: 64-fold change	70.48	80.87	0	
Visit 7/Day 180: 4-fold change	89.72	95.69	0	
Visit 7/Day 180: 8-fold change	88.79	95.69	0	
Visit 7/Day 180: 16-fold change	87.85	95.69	0	
Visit 7/Day 180: 64-fold change	55.14	73.28	0	
Visit 8/Day 365: 4-fold change	89.62	95.65	0	
Visit 8/Day 365: 8-fold change	88.68	95.65	0	
Visit 8/Day 365: 16-fold change	85.85	94.78	0	
Visit 8/Day 365: 64-fold change	69.81	86.96	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 30. Percentage of participants reaching an at least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific neutralizing antibody titers compared to baseline stratified by age stratum

End point title	30. Percentage of participants reaching an at least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific neutralizing antibody titers compared to baseline stratified by age stratum
End point description:	Percentage of Participants Reaching a 4-/8-/16-/64-Fold Change in Titers by Visit by Age Group and Trial Arm.
End point type	Secondary
End point timeframe:	at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15: 4-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 4/Day 15: 8-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 4/Day 15: 16-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 4/Day 15: 64-fold change - 7 - 11 Years	75.86	94.44	0	
Visit 5/Day 29: 4-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 5/Day 29: 8-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 5/Day 29: 16-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 5/Day 29: 64-fold change - 7 - 11 Years	86.21	100.00	0	
Visit 6/Day 85: 4-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 6/Day 85: 8-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 6/Day 85: 16-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 6/Day 85: 64-fold change - 7 - 11 Years	75.86	85.71	0	
Visit 7/Day 180: 4-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 7/Day 180: 8-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 7/Day 180: 16-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 7/Day 180: 64-fold change - 7 - 11 Years	65.52	69.44	0	
Visit 8/Day 365: 4-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 8/Day 365: 8-fold change - 7 - 11 Years	89.66	100.00	0	
Visit 8/Day 365: 16-fold change - 7 - 11 Years	89.66	97.22	0	
Visit 8/Day 365: 64-fold change - 7 - 11 Years	72.41	88.89	0	
Visit 4/Day 15: 4-fold change - 3 - 6 Years	92.31	97.44	0	
Visit 4/Day 15: 8-fold change - 3 - 6 Years	92.31	97.44	0	
Visit 4/Day 15: 16-fold change - 3 - 6 Years	92.31	97.44	0	
Visit 4/Day 15: 64-fold change - 3 - 6 Years	82.05	89.74	0	
Visit 5/Day 29: 4-fold change - 3 - 6 Years	92.50	97.44	0	
Visit 5/Day 29: 8-fold change - 3 - 6 Years	92.50	97.44	0	
Visit 5/Day 29: 16-fold change - 3 - 6 Years	92.50	97.44	0	

Visit 5/Day 29: 64-fold change - 3 - 6 Years	90.00	97.44	0	
Visit 6/Day 85: 4-fold change - 3 - 6 Years	94.59	97.44	0	
Visit 6/Day 85: 8-fold change - 3 - 6 Years	94.59	97.44	0	
Visit 6/Day 85: 16-fold change - 3 - 6 Years	91.89	97.44	0	
Visit 6/Day 85: 64-fold change - 3 - 6 Years	70.27	79.49	0	
Visit 7/Day 180: 4-fold change - 3 - 6 Years	95.00	97.44	0	
Visit 7/Day 180: 8-fold change - 3 - 6 Years	92.50	97.44	0	
Visit 7/Day 180: 16-fold change - 3 - 6 Years	90.00	97.44	0	
Visit 7/Day 180: 64-fold change - 3 - 6 Years	45.00	71.79	0	
Visit 8/Day 365: 4-fold change - 3 - 6 Years	92.50	97.44	0	
Visit 8/Day 365: 8-fold change - 3 - 6 Years	92.50	97.44	0	
Visit 8/Day 365: 16-fold change - 3 - 6 Years	87.50	97.44	0	
Visit 8/Day 365: 64-fold change - 3 - 6 Years	62.50	84.62	0	
Visit 4/Day 15: 4-fold change - 1 - 2 Years	83.78	89.74	0	
Visit 4/Day 15: 8-fold change - 1 - 2 Years	83.78	89.74	0	
Visit 4/Day 15: 16-fold change - 1 - 2 Years	81.08	89.74	0	
Visit 4/Day 15: 64-fold change - 1 - 2 Years	75.68	84.62	0	
Visit 5/Day 29: 4-fold change - 1 - 2 Years	86.84	89.74	0	
Visit 5/Day 29: 8-fold change - 1 - 2 Years	84.21	89.74	0	
Visit 5/Day 29: 16-fold change - 1 - 2 Years	84.21	89.74	0	
Visit 5/Day 29: 64-fold change - 1 - 2 Years	84.21	89.74	0	
Visit 6/Day 85: 4-fold change - 1 - 2 Years	83.33	90.00	0	
Visit 6/Day 85: 8-fold change - 1 - 2 Years	83.33	90.00	0	
Visit 6/Day 85: 16-fold change - 1 - 2 Years	83.33	90.00	0	
Visit 6/Day 85: 64-fold change - 1 - 2 Years	66.67	77.50	0	
Visit 7/Day 180: 4-fold change - 1 - 2 Years	83.33	92.31	0	
Visit 7/Day 180: 8-fold change - 1 - 2 Years	83.33	92.31	0	
Visit 7/Day 180: 16-fold change - 1 - 2 Years	83.33	92.31	0	
Visit 7/Day 180: 64-fold change - 1 - 2 Years	58.33	79.49	0	
Visit 8/Day 365: 4-fold change - 1 - 2 Years	85.71	89.74	0	
Visit 8/Day 365: 8-fold change - 1 - 2 Years	82.86	89.74	0	

Visit 8/Day 365: 16-fold change - 1 -2 Years	80.00	89.74	0	
Visit 8/Day 365: 64-fold change - 1 -2 Years	74.29	87.18	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 31. Percentage of Participants Reaching an at Least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific Neutralizing Antibody Titers Compared to Baseline by dose

End point title	31. Percentage of Participants Reaching an at Least 4-fold, 8-fold, 16-fold or 64-fold change in CHIKV-specific Neutralizing Antibody Titers Compared to Baseline by dose
-----------------	---

End point description:

Percentage of Participants Reaching a 4-/8-/16-/64-Fold Change in Titers by Visit Pooled by Trial Arm.

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

End point timeframe:

at Day 15, Day 29, Day 85, Day 180 and Month 12

End point values	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	107	115	53	
Units: percentage of participants				
number (not applicable)				
Visit 4/Day 15: 4-fold change	88.57	95.61	0	
Visit 4/Day 15: 8-fold change	88.57	95.61	0	
Visit 4/Day 15: 16-fold change	87.62	95.61	0	
Visit 4/Day 15: 64-fold change	78.10	89.47	0	
Visit 5/Day 29: 4-fold change	89.72	95.61	0	
Visit 5/Day 29: 8-fold change	88.79	95.61	0	
Visit 5/Day 29: 16-fold change	88.79	95.61	0	
Visit 5/Day 29: 64-fold change	86.92	95.61	0	
Visit 6/Day 85: 4-fold change	89.22	95.61	0	
Visit 6/Day 85: 8-fold change	89.22	95.61	0	
Visit 6/Day 85: 16-fold change	88.24	95.61	0	
Visit 6/Day 85: 64-fold change	70.59	80.70	0	
Visit 7/Day 180: 4-fold change	89.52	96.49	0	
Visit 7/Day 180: 8-fold change	88.57	96.49	0	
Visit 7/Day 180: 16-fold change	87.62	96.49	0	
Visit 7/Day 180: 64-fold change	55.24	73.68	0	
Visit 8/Day 365: 4-fold change	89.42	95.61	0	
Visit 8/Day 365: 8-fold change	88.46	95.61	0	
Visit 8/Day 365: 16-fold change	85.58	94.74	0	
Visit 8/Day 365: 64-fold change	69.23	86.84	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

- Up to 14 days post-vaccination: solicited local and systemic AEs
- Up to M6 and M12 post-vaccination: Unsolicited AEs
- Up to M6 and M12 post-vaccination: SAEs
- Within 2 to 21 days post-vaccination: early onset AESI
- 22 days post-vaccination till*

Adverse event reporting additional description:

*trial end: late onset AESI

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

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	CHIKV vaccine Half Dose
-----------------------	-------------------------

Reporting group description:

CHIKV vaccine Half Dose formulation (target 3.7 log 10 TCID50 per 0.5 mL)

Reporting group title	CHIKV vaccine Full Dose
-----------------------	-------------------------

Reporting group description:

CHIKV vaccine Full Dose formulation (target 4.0 log 10 TCID50 per 0.5 mL)

Reporting group title	Nimenrix
-----------------------	----------

Reporting group description:

Nimenrix is a conjugate vaccine indicated for the active immunization of individuals from the age of 6 weeks against invasive meningococcal disease caused by *Neisseria meningitidis* groups A, C, W-135, and Y. Nimenrix is present as powder and solvent for solution for injection in pre-filled syringe. The reconstituted vaccine is a clear colourless solution. Nimenrix should be used in accordance with available official recommendations. Primary immunization in infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered.

Serious adverse events	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 119 (1.68%)	4 / 124 (3.23%)	1 / 61 (1.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Immune system disorders			
Drug hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 119 (0.00%)	1 / 124 (0.81%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Faecaloma			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 119 (0.00%)	1 / 124 (0.81%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthmatic crisis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 119 (0.00%)	2 / 124 (1.61%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis perforated			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 119 (0.84%)	0 / 124 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 119 (0.84%)	0 / 124 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 119 (0.00%)	0 / 124 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	CHIKV vaccine Half Dose	CHIKV vaccine Full Dose	Nimenrix
Total subjects affected by non-serious adverse events			
subjects affected / exposed	93 / 119 (78.15%)	98 / 124 (79.03%)	48 / 61 (78.69%)
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	19 / 119 (15.97%) 23	22 / 124 (17.74%) 24	8 / 61 (13.11%) 9
General disorders and administration site conditions Injection site pain subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	19 / 119 (15.97%) 26 24 / 119 (20.17%) 26	16 / 124 (12.90%) 22 19 / 124 (15.32%) 20	7 / 61 (11.48%) 11 6 / 61 (9.84%) 6
Gastrointestinal disorders Diarrhoea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all)	6 / 119 (5.04%) 6 8 / 119 (6.72%) 8 8 / 119 (6.72%) 8	11 / 124 (8.87%) 15 12 / 124 (9.68%) 13 2 / 124 (1.61%) 2	7 / 61 (11.48%) 9 3 / 61 (4.92%) 4 1 / 61 (1.64%) 1
Respiratory, thoracic and mediastinal disorders Rhinitis allergic alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Allergic cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	11 / 119 (9.24%) 14 3 / 119 (2.52%) 4	13 / 124 (10.48%) 15 1 / 124 (0.81%) 1	8 / 61 (13.11%) 13 4 / 61 (6.56%) 4
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	8 / 119 (6.72%) 8	4 / 124 (3.23%) 4	1 / 61 (1.64%) 1
Infections and infestations			

Nasopharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	60 / 119 (50.42%) 103	59 / 124 (47.58%) 126	27 / 61 (44.26%) 52
Viral infection alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	6 / 119 (5.04%) 10	8 / 124 (6.45%) 9	9 / 61 (14.75%) 11
Gastroenteritis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	2 / 119 (1.68%) 2	8 / 124 (6.45%) 8	2 / 61 (3.28%) 2
Tonsillitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	6 / 119 (5.04%) 6	4 / 124 (3.23%) 4	1 / 61 (1.64%) 1
Metabolism and nutrition disorders Decreased appetite alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	4 / 119 (3.36%) 4	9 / 124 (7.26%) 9	1 / 61 (1.64%) 1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported