Clinical trial results:
A Phase 2 Randomized, Multi-Center Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Immunogenicity of the V920 (rVSVG-ZEBOV-GP) Ebola Virus Vaccine Candidate in HIV-Infected Adults and Adolescents

Summary

EudraCT number	2016-004853-34
Trial protocol	Outside EU/EEA
Global end of trial date	03 March 2023

Results information

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

Trial information

Trial identification

Sponsor protocol code	CT1401-B

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03031912
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Canadian Immunization Research Network (CIRN) Project Management Office
Sponsor organisation address	5850/5980 University Avenue, Halifax, Canada, B3K 6R8
Public contact	Canadian Immunization Research Network, Canadian Immunization Research Network, 1 902470-8141, ccfv@iwk.nshealth.ca
Scientific contact	Canadian Immunization Research Network, Canadian Immunization Research Network, 1 902470-8141, ccfv@iwk.nshealth.ca

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001786-PIP01-15
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 March 2023
Global end of trial reached?	Yes
Global end of trial date	03 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluate the safety and tolerability of V920 in HIV-infected adults and adolescents.

Evaluate the immunogenicity of V920 via ZEBOV- specific antibody responses induced by V920 in HIV-infected adults and adolescents.

Protection of trial subjects:

This study was conducted in accordance with Good Clinical Practice (GCP) and applicable regulatory requirements. Safety monitoring occurred throughout the study (SAEs, AEs) up to 1-year post-vaccination.

Background therapy:

All participants were on antiretroviral therapy with an undetectable viral load (< 40 c/ml).

Evidence for comparator:

A placebo was used as the comparator as there was no other standard of care Ebola vaccine available at the time of the study start.

Actual start date of recruitment	01 August 2017
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	Canada: 26
Country: Number of subjects enrolled	Senegal: 73
Country: Number of subjects enrolled	Burkina Faso: 152
Worldwide total number of subjects	251
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)	65
Adults (18-64 years)	184
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First participant was enrolled in November 2017, and the last participant was enrolled in March 2022.

Pre-assignment

Screening details:

A total of 641 potential participants were screened, 251 were randomized and 250 received study vaccine or placebo.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: V920

Arm description:

Adults with screening CD4 cells/mm3 ≥ 500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Arm type	Experimental
Investigational medicinal product name	V920 Ebola Virus Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

rVSVΔG-ZEBOV-GP vaccine (V920) will be administered as an IM injection. V920 should be removed from the freezer and thawed at room temperature (not 2-8°C) for approximately 10-15 minutes. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study vaccine/placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. All subjects will receive, on Day 0 either the V920 (rVSVΔG-ZEBOV-GP) vaccine at a dose of ≥2x107 PFU in 1mL IM, or normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 1: Placebo

Arm description:

Adults with screening CD4 cells/mm3 ≥500 randomly assigned to receive placebo.

Arm type	Placebo
Investigational medicinal product name	Normal Saline (0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

Placebo is administered as an IM injection. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. Placebo recipients receive normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 2: V920

Arm description:

Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Arm type	Experimental
Investigational medicinal product name	V920 Ebola Virus Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

rVSVΔG-ZEBOV-GP vaccine (V920) will be administered as an IM injection. V920 should be removed from the freezer and thawed at room temperature (not 2-8°C) for approximately 10-15 minutes. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study vaccine/placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. All subjects will receive, on Day 0 either the V920 (rVSVΔG-ZEBOV-GP) vaccine at a dose of ≥2x107 PFU in 1mL IM, or normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 2: Placebo

Arm description:

Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive placebo.

Arm type	Placebo
Investigational medicinal product name	Normal Saline (0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

Placebo is administered as an IM injection. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. Placebo recipients receive normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 3: V920

Arm description:

Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Arm type	Experimental
Investigational medicinal product name	V920 Ebola Virus Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

rVSVΔG-ZEBOV-GP vaccine (V920) will be administered as an IM injection. V920 should be removed from the freezer and thawed at room temperature (not 2-8°C) for approximately 10-15 minutes. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study vaccine/placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. All subjects will receive, on Day 0 either the V920 (rVSVΔG-ZEBOV-GP) vaccine at a dose of ≥2x107 PFU in 1mL IM, or normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 3: Placebo

Arm description:

Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive placebo.

Arm type	Placebo
Investigational medicinal product name	Normal Saline (0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

Placebo is administered as an IM injection. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. Placebo recipients receive normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 4: V920

Arm description:

Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Arm type	Experimental
Investigational medicinal product name	V920 Ebola Virus Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

rVSVΔG-ZEBOV-GP vaccine (V920) will be administered as an IM injection. V920 should be removed from the freezer and thawed at room temperature (not 2-8°C) for approximately 10-15 minutes. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study vaccine/placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. All subjects will receive, on Day 0 either the V920 (rVSVΔG-ZEBOV-GP) vaccine at a dose of ≥2x107 PFU in 1mL IM, or normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 4: Placebo

Arm description:

Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo.

Arm type	Placebo
Investigational medicinal product name	Normal Saline (0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

Placebo is administered as an IM injection. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. Placebo recipients receive normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 5: V920

Arm description:

Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

This cohort received 2 doses 56 days apart.

Arm type	Experimental

Investigational medicinal product name	V920 Ebola Virus Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

rVSVΔG-ZEBOV-GP vaccine (V920) will be administered as an IM injection. V920 should be removed from the freezer and thawed at room temperature (not 2-8°C) for approximately 10-15 minutes. The thawed vial should then be gently inverted several times prior to withdrawal with the syringe. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study vaccine/placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. All subjects will receive, on Day 0 either the V920 (rVSVΔG-ZEBOV-GP) vaccine at a dose of ≥2x107 PFU in 1mL IM, or normal saline (0.9%) placebo control in 1mL volume.

Arm title	Cohort 5: Placebo

Arm description:

Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo.

This cohort received 2 doses 56 days apart.

Arm type	Placebo
Investigational medicinal product name	Normal Saline (0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Injection , Intramuscular use

Dosage and administration details:

Placebo is administered as an IM injection. An unblinded pharmacist (or other designated unblinded person) at the site will be required to prepare the study placebo in order to maintain the blinding. Both study vaccine and placebo are clear, and indistinguishable from one another once in the syringe. Once the syringe is prepared, the blinded personnel will administer the study vaccine/placebo to the subject. Placebo recipients receive normal saline (0.9%) placebo control in 1mL volume.

Number of subjects in period 1	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920
Started	41	10	40
Completed	41	10	40

Number of subjects in period 1	Cohort 2: Placebo	Cohort 3: V920	Cohort 3: Placebo
Started	10	41	9
Completed	10	41	9

Number of subjects in period 1	Cohort 4: V920	Cohort 4: Placebo	Cohort 5: V920
Started	40	10	40
Completed	40	10	40

Number of subjects in period 1	Cohort 5: Placebo
Started	10

Completed	10

Baseline characteristics

Reporting groups	
Reporting group title	Cohort 1: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥ 500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 1: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥500 randomly assigned to receive placebo.	
Reporting group title	Cohort 2: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 2: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive placebo.	
Reporting group title	Cohort 3: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 3: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive placebo.	
Reporting group title	Cohort 4: V920
Reporting group description:	
Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 4: Placebo
Reporting group description:	
Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo.	
Reporting group title	Cohort 5: V920
Reporting group description:	
Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine. This cohort received 2 doses 56 days apart.	
Reporting group title	Cohort 5: Placebo
Reporting group description:	
Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo. This cohort received 2 doses 56 days apart.	

Reporting group values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920
Number of subjects	41	10	40
Age categorical Units: Subjects			
Adolescents (12-17 years)	0	0	0
Adults (18-65 years)	40	10	39
Adults (>65 years)	1	0	1

Age continuous			
Units: years			
arithmetic mean	52.1	48.9	48.1
standard deviation	± 8.0	± 8.6	± 8.3
Gender categorical			
Units: Subjects			
Female	17	6	24
Male	24	4	16
Race/Ethnicity			
Units: Subjects			
Black or African American	21	5	39
Multiple - Asian, White	0	1	0
White	20	4	1

Reporting group values	Cohort 2: Placebo	Cohort 3: V920	Cohort 3: Placebo
Number of subjects	10	41	9
Age categorical			
Units: Subjects			
Adolescents (12-17 years)	0	0	0
Adults (18-65 years)	10	41	9
Adults (>65 years)	0	0	0
Age continuous			
Units: years			
arithmetic mean	49.9	46.6	44.1
standard deviation	± 7.0	± 11.1	± 8.8
Gender categorical			
Units: Subjects			
Female	7	18	6
Male	3	23	3
Race/Ethnicity			
Units: Subjects			
Black or African American	10	41	9
Multiple - Asian, White	0	0	0
White	0	0	0

Reporting group values	Cohort 4: V920	Cohort 4: Placebo	Cohort 5: V920
Number of subjects	40	10	40
Age categorical			
Units: Subjects			
Adolescents (12-17 years)	40	10	12
Adults (18-65 years)	0	0	28
Adults (>65 years)	0	0	0
Age continuous			
Units: years			
arithmetic mean	15.0	14.5	33.1
standard deviation	± 1.5	± 1.4	± 15.2
Gender categorical			
Units: Subjects			
Female	20	7	21
Male	20	3	19

Race/Ethnicity Units: Subjects			
Black or African American	40	10	40
Multiple - Asian, White	0	0	0
White	0	0	0

Reporting group values	Cohort 5: Placebo	Total	
Number of subjects	10	251	
Age categorical Units: Subjects			
Adolescents (12-17 years)	3	65	
Adults (18-65 years)	7	184	
Adults (>65 years)	0	2	
Age continuous Units: years			
arithmetic mean	33.8		
standard deviation	± 19	-	
Gender categorical Units: Subjects			
Female	4	130	
Male	6	121	
Race/Ethnicity Units: Subjects			
Black or African American	10	225	
Multiple - Asian, White	0	1	
White	0	25	

End points

End points reporting groups

Reporting group title	Cohort 1: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥ 500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 1: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥500 randomly assigned to receive placebo.	
Reporting group title	Cohort 2: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 2: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive placebo.	
Reporting group title	Cohort 3: V920
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 3: Placebo
Reporting group description:	
Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive placebo.	
Reporting group title	Cohort 4: V920
Reporting group description:	
Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.	
Reporting group title	Cohort 4: Placebo
Reporting group description:	
Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo.	
Reporting group title	Cohort 5: V920
Reporting group description:	
Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine. This cohort received 2 doses 56 days apart.	
Reporting group title	Cohort 5: Placebo
Reporting group description:	
Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo. This cohort received 2 doses 56 days apart.	

Primary: Number of participants with solicited adverse events following V920 vaccination

End point title	Number of participants with solicited adverse events following V920 vaccination[1]

End point description:

The number of participants with general solicited local (at the injection site) and systemic adverse events following vaccination will be summarized.

Local AES are pain at injection site, redness/erythema at injection site, swelling at injection site Systemic AEs are arthralgia, joint swelling, feeling hot, sweats, chills, fatigue, diarrhea,

nausea/vomiting, headache, abdominal pain, myalgia, rash, blisters, pyrexia and hyperhidrosis.

End point type	Primary

End point timeframe:

From vaccine administration up to day 14 following 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: The analyses for this endpoint were descriptive only, based on counts and percentages. No statistical testing was performed.

End point values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	10	40	10
Units: Participants				
Local - injection site erythema	5	1	2	1
Local - Injection site pain	22	3	20	3
Local - Injection site swelling	4	0	0	1
Systemic - Abdominal pain	4	0	5	1
Systemic - Arthralgia	14	0	16	2
Systemic - Blister	0	0	1	0
Systemic - Chills	14	0	4	1
Systemic - Diarrhea	10	1	2	1
Systemic - Fatigue	21	3	18	5
Systemic - Feeling hot	11	0	7	2
Systemic - Headache	23	4	21	2
Systemic - Hyperhidrosis	11	0	1	0
Systemic - Joint swelling	0	0	0	1
Systemic - Myalgia	12	2	8	1
Systemic - Nausea	10	1	3	2
Systemic - Pyrexia	5	0	1	0
Systemic - Rash	1	1	2	2

End point values	Cohort 3: V920	Cohort 3: Placebo	Cohort 4: V920	Cohort 4: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	9	40	10
Units: Participants				
Local - injection site erythema	2	0	0	0
Local - Injection site pain	24	1	34	3
Local - Injection site swelling	2	0	4	1
Systemic - Abdominal pain	4	1	4	1
Systemic - Arthralgia	7	1	3	0
Systemic - Blister	0	0	1	0
Systemic - Chills	8	1	3	0
Systemic - Diarrhea	2	1	1	0
Systemic - Fatigue	24	1	8	1
Systemic - Feeling hot	8	1	10	3
Systemic - Headache	20	2	22	5
Systemic - Hyperhidrosis	3	1	4	0

Systemic - Joint swelling	0	0	0	0
Systemic - Myalgia	2	0	3	0
Systemic - Nausea	3	0	3	0
Systemic - Pyrexia	0	0	4	0
Systemic - Rash	1	1	2	1

End point values	Cohort 5: V920	Cohort 5: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Participants				
Local - injection site erythema	0	0		
Local - Injection site pain	30	2		
Local - Injection site swelling	1	1		
Systemic - Abdominal pain	8	1		
Systemic - Arthralgia	10	1		
Systemic - Blister	0	0		
Systemic - Chills	6	0		
Systemic - Diarrhea	2	0		
Systemic - Fatigue	20	1		
Systemic - Feeling hot	15	1		
Systemic - Headache	23	0		
Systemic - Hyperhidrosis	7	1		
Systemic - Joint swelling	0	0		
Systemic - Myalgia	10	0		
Systemic - Nausea	9	0		
Systemic - Pyrexia	1	0		
Systemic - Rash	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with arthralgia, blister, joint swelling, pyrexia or rash following V920 vaccination

End point title	Number of participants with arthralgia, blister, joint swelling, pyrexia or rash following V920 vaccination[2]

End point description:

The number of participants with the following solicited systemic adverse events following vaccination: arthralgia, blister, joint swelling, pyrexia or rash.

End point type	Primary

End point timeframe:

From vaccine administration up to 42 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: The analyses for this endpoint were descriptive only, based on counts and percentages. No statistical testing was performed.

End point values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	10	40	10
Units: Participants				
Arthralgia	9	2	15	2
Blister	1	0	0	0
Joint swelling	0	0	1	1
Pyrexia	8	0	2	0
Rash	0	1	2	0

End point values	Cohort 3: V920	Cohort 3: Placebo	Cohort 4: V920	Cohort 4: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	9	40	10
Units: Participants				
Arthralgia	6	0	0	0
Blister	0	0	1	0
Joint swelling	0	0	0	0
Pyrexia	1	0	7	0
Rash	0	0	2	0

End point values	Cohort 5: V920	Cohort 5: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Participants				
Arthralgia	6	1		
Blister	0	0		
Joint swelling	0	0		
Pyrexia	3	0		
Rash	2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with unsolicited adverse events following V920 vaccination

End point title	Number of participants with unsolicited adverse events following V920 vaccination[3]

End point description:

The number of participants with unsolicited adverse events following vaccination.

End point type	Primary

End point timeframe:

From vaccine administration up to day 42 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: The analyses for this endpoint were descriptive only, based on counts and percentages. No statistical testing was performed.

End point values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	10	40	10
Units: Participants				
Blood & lymphatic system disorders-Lymphadenopathy	1	0	0	0
Cardiac disorders - Angina pectoris	0	0	0	0
Ear and labyrinth disorders - Cerumen impaction	0	0	0	0
Eye disorders - Conjunctivitis allergic	0	0	0	0
Eye irritation	0	0	0	0
Eye disorders - Eye pain	0	0	0	0
Gastrointestinal disorders - Abdominal pain	1	0	0	0
Gastrointestinal disorders - Abdominal pain upper	0	0	0	0
Gastrointestinal disorders - Dental caries	1	1	0	0
Gastrointestinal disorders - Diarrhea	4	1	0	0
Gastrointestinal disorders - Dyspepsia	1	0	0	0
Gastrointestinal disorders - Gastroduodenal ulcer	1	0	0	0
Gastrointestinal disorders - Malpositioned teeth	1	0	0	0
Gastrointestinal disorders - Oral papule	0	0	0	0
Gastrointestinal disorders - Peptic ulcer	0	0	1	0
Gastrointestinal disorders - Toothache	0	0	2	0
Chest pain	0	0	1	0
Fatigue	0	2	1	0
Ill defined disorder	0	0	0	0
Injection site induration	1	0	0	0
Pain	0	0	2	1
Tenderness	0	0	0	0
Amoebic dysentery	0	0	0	0
Bronchitis	1	1	0	0
Conjunctivitis bacterial	0	0	0	0
Cutaneous leishmaniasis	0	0	0	0
Cystitis	1	0	0	0
Furuncle	1	0	1	0
Gastroenteritis	1	0	1	1
Influenza	1	1	0	1
Malaria	5	1	1	0
Nasopharyngitis	3	1	0	0
Orchitis	0	0	0	0
Otitis media chronic	0	0	0	0
Parasitic gastroenteritis	0	0	0	0

Paronychia	0	0	0	0
Pilonidal disease	1	0	0	0
Pneumonia	1	0	0	0
Rhinitis	0	0	3	0
Sinobronchitis	0	0	1	0
Tinea pedis	0	0	0	0
Tonsillitis	1	0	0	0
Tooth abscess	0	0	0	0
Tooth infection	0	0	0	0
Typhoid fever	0	0	0	0
Upper respiratory tract infection	1	0	0	0
Urinary tract infection	0	0	0	0
Vulvovaginal mycotic infection	0	0	0	0
Ankle fracture	0	0	0	0
Limb injury	0	0	0	0
Thermal burn	0	0	1	0
Decreased appetite	2	0	1	0
Back pain	1	0	0	0
Bursitis	1	0	0	0
Myalgia	0	1	0	0
Pain in extremity	0	0	0	0
Torticollis	0	0	0	0
Burning sensation	1	0	0	0
Carpal tunnel syndrome	1	0	0	0
Dizziness	0	0	4	0
Headache	1	0	3	0
Cervicobrachial syndrome	0	1	0	0
Intercostal neuralgia	1	0	0	0
Paraesthesia	0	0	1	0
Sciatica	0	1	0	0
Insomnia	2	0	1	0
Breast pain	1	0	0	0
Dysmenorrhoea	0	0	0	0
Heavy menstrual bleeding	0	0	1	0
Vaginal discharge	1	0	0	0
Bronchopneumopathy	0	0	0	0
Cough	2	0	0	0
Lung disorder	1	0	0	0
Oropharyngeal pain	0	0	0	0
Acne	0	0	0	0
Ecchymosis	1	0	0	0
Hyperhidrosis	0	0	0	0
Intertrigo	0	0	0	0
Prurigo	0	0	0	0
Pruritus	3	1	0	1
Diastolic hypertension	1	0	0	1
Hypertension	0	0	0	0
Gastrointestinal Disorder	1	0	0	0
Conjunctivitis	0	0	1	0

End point values	Cohort 3: V920	Cohort 3: Placebo	Cohort 4: V920	Cohort 4: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	9	40	10
Units: Participants				
Blood & lymphatic system disorders-Lymphadenopathy	0	0	0	0
Cardiac disorders - Angina pectoris	1	0	0	0
Ear and labyrinth disorders - Cerumen impaction	0	0	1	0
Eye disorders - Conjunctivitis allergic	2	0	1	0
Eye irritation	0	0	1	0
Eye disorders - Eye pain	0	0	1	0
Gastrointestinal disorders - Abdominal pain	0	0	1	1
Gastrointestinal disorders - Abdominal pain upper	1	0	0	0
Gastrointestinal disorders - Dental caries	1	0	1	0
Gastrointestinal disorders - Diarrhea	1	0	0	0
Gastrointestinal disorders - Dyspepsia	0	0	0	0
Gastrointestinal disorders - Gastroduodenal ulcer	1	0	0	0
Gastrointestinal disorders - Malpositioned teeth	0	0	0	0
Gastrointestinal disorders - Oral papule	1	0	0	0
Gastrointestinal disorders - Peptic ulcer	0	0	0	0
Gastrointestinal disorders - Toothache	0	0	2	0
Chest pain	0	0	0	0
Fatigue	1	0	0	0
Ill defined disorder	0	0	2	0
Injection site induration	0	0	0	0
Pain	1	0	0	0
Tenderness	0	0	0	0
Amoebic dysentery	0	1	0	0
Bronchitis	2	2	2	0
Conjunctivitis bacterial	0	0	1	0
Cutaneous leishmaniasis	0	1	0	0
Cystitis	0	0	0	0
Furuncle	0	1	0	0
Gastroenteritis	0	0	0	0
Influenza	0	0	0	0
Malaria	1	0	4	1
Nasopharyngitis	0	0	0	0
Orchitis	0	1	0	0
Otitis media chronic	0	0	0	1
Parasitic gastroenteritis	1	0	0	0
Paronychia	0	0	1	0
Pilonidal disease	0	0	0	0
Pneumonia	0	0	0	0
Rhinitis	4	1	2	0

Sinobronchitis	4	1	3	0
Tinea pedis	1	0	0	0
Tonsillitis	0	0	0	0
Tooth abscess	1	0	0	0
Tooth infection	2	0	0	0
Typhoid fever	1	0	0	0
Upper respiratory tract infection	0	0	0	0
Urinary tract infection	1	0	0	0
Vulvovaginal mycotic infection	1	0	0	0
Ankle fracture	1	0	0	0
Limb injury	1	0	0	0
Thermal burn	0	0	0	0
Decreased appetite	0	0	0	0
Back pain	0	1	0	0
Bursitis	0	0	0	0
Myalgia	0	0	0	0
Pain in extremity	1	0	0	0
Torticollis	0	0	0	0
Burning sensation	0	0	0	0
Carpal tunnel syndrome	0	0	0	0
Dizziness	3	0	1	0
Headache	2	0	1	1
Cervicobrachial syndrome	0	0	0	0
Intercostal neuralgia	0	0	0	0
Paraesthesia	1	0	0	0
Sciatica	0	0	0	0
Insomnia	0	0	0	0
Breast pain	0	0	0	0
Dysmenorrhoea	0	0	1	1
Heavy menstrual bleeding	0	0	0	0
Vaginal discharge	0	0	0	0
Bronchopneumopathy	0	1	0	0
Cough	0	1	5	1
Lung disorder	0	0	1	0
Oropharyngeal pain	0	0	1	0
Acne	1	0	0	0
Ecchymosis	0	0	0	0
Hyperhidrosis	1	0	0	0
Intertrigo	1	0	0	0
Prurigo	1	0	1	0
Pruritus	0	0	1	0
Diastolic hypertension	0	0	0	0
Hypertension	1	0	0	0
Gastrointestinal Disorder	0	0	0	0
Conjunctivitis	0	1	2	0

End point values	Cohort 5: V920	Cohort 5: Placebo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Participants				
Blood & lymphatic system disorders- Lymphadenopathy	0	0		
Cardiac disorders - Angina pectoris	0	0		
Ear and labyrinth disorders - Cerumen impaction	0	0		
Eye disorders - Conjunctivitis allergic	0	0		
Eye irritation	0	0		
Eye disorders - Eye pain	0	0		
Gastrointestinal disorders - Abdominal pain	1	0		
Gastrointestinal disorders - Abdominal pain upper	1	0		
Gastrointestinal disorders - Dental caries	1	0		
Gastrointestinal disorders - Diarrhea	0	1		
Gastrointestinal disorders - Dyspepsia	0	0		
Gastrointestinal disorders - Gastroduodenal ulcer	0	0		
Gastrointestinal disorders - Malpositioned teeth	0	0		
Gastrointestinal disorders - Oral papule	0	0		
Gastrointestinal disorders - Peptic ulcer	0	0		
Gastrointestinal disorders - Toothache	1	0		
Chest pain	0	0		
Fatigue	0	0		
Ill defined disorder	0	0		
Injection site induration	0	0		
Pain	0	0		
Tenderness	0	0		
Amoebic dysentery	0	0		
Bronchitis	1	0		
Conjunctivitis bacterial	0	0		
Cutaneous leishmaniasis	0	0		
Cystitis	0	0		
Furuncle	0	0		
Gastroenteritis	0	0		
Influenza	0	0		
Malaria	2	0		
Nasopharyngitis	0	0		
Orchitis	0	0		
Otitis media chronic	0	0		
Parasitic gastroenteritis	0	0		
Paronychia	0	0		
Pilonidal disease	0	0		
Pneumonia	0	0		
Rhinitis	3	0		
Sinobronchitis	1	0		
Tinea pedis	0	0		
Tonsillitis	0	0		
Tooth abscess	0	0		
Tooth infection	0	0		

Typhoid fever	0	0		
Upper respiratory tract infection	0	0		
Urinary tract infection	0	0		
Vulvovaginal mycotic infection	0	0		
Ankle fracture	0	0		
Limb injury	2	0		
Thermal burn	0	0		
Decreased appetite	0	0		
Back pain	0	0		
Bursitis	0	0		
Myalgia	0	0		
Pain in extremity	0	0		
Torticollis	1	0		
Burning sensation	0	0		
Carpal tunnel syndrome	0	0		
Dizziness	0	1		
Headache	3	0		
Cervicobrachial syndrome	0	0		
Intercostal neuralgia	0	0		
Paraesthesia	0	0		
Sciatica	0	0		
Insomnia	0	0		
Breast pain	0	0		
Dysmenorrhoea	0	0		
Heavy menstrual bleeding	0	0		
Vaginal discharge	0	0		
Bronchopneumopathy	0	0		
Cough	3	1		
Lung disorder	0	0		
Oropharyngeal pain	0	0		
Acne	0	0		
Ecchymosis	0	0		
Hyperhidrosis	0	0		
Intertrigo	0	0		
Prurigo	0	0		
Pruritus	1	1		
Diastolic hypertension	0	0		
Hypertension	1	0		
Gastrointestinal Disorder	0	0		
Conjunctivitis	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events Following V920 Vaccination

End point title	Number of Participants With Serious Adverse Events Following V920 Vaccination[4]

End point description:

The number of participants with vaccine-related serious adverse events following V920 vaccination.

End point type	Primary

End point timeframe:

From vaccine administration up to day 365 following 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: The analyses for this endpoint were descriptive only, based on counts and percentages. No statistical testing was performed.

End point values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	10	40	10
Units: Participants	2	0	0	0

End point values	Cohort 3: V920	Cohort 3: Placebo	Cohort 4: V920	Cohort 4: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	9	40	10
Units: Participants	1	0	0	1

End point values	Cohort 5: V920	Cohort 5: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers Induced by V920

End point title	Geometric Mean Titers Induced by V920

End point description:

Geometric Mean Titers (GMTs) for ZEBOV-specific antibodies at Day 28 were calculated for each treatment group, along with two-sided 95% CIs, by exponentiating the corresponding log-transformed mean and two-sided 95% confidence limits. Cohorts 1-5.

End point type	Primary

End point timeframe:

Day 28 postvaccination

End point values	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920	Cohort 2: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	10	40	10
Units: Titer				
geometric mean (confidence interval 95%)	1655.0 (1151.4 to 2378.9)	18.1 (8.7 to 37.3)	1124.6 (821.0 to 1540.4)	26.8 (13.8 to 52.0)

End point values	Cohort 3: V920	Cohort 3: Placebo	Cohort 4: V920	Cohort 4: Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	9	40	10
Units: Titer				
geometric mean (confidence interval 95%)	868.8 (679.0 to 1111.6)	29.7 (17.5 to 50.2)	1432.8 (1091.0 to 1881.8)	30.4 (17.6 to 52.4)

End point values	Cohort 5: V920	Cohort 5: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Titer				
geometric mean (confidence interval 95%)	1191.8 (865.7 to 1640.6)	43.1 (22.8 to 81.8)		

Statistical analyses

Statistical analysis title	GMTs for ZEBOV-specific antibodies

Statistical analysis description:

Geometric Mean Titers (GMTs) for ZEBOV-specific antibodies at Day 28 were calculated for each treatment group, cohorts 1-5 combined, along with two-sided 95% CIs. Mean fold difference between treatment groups was compared using ANOVA.

Comparison groups	Cohort 1: V920 v Cohort 1: Placebo v Cohort 2: V920 v Cohort 2: Placebo v Cohort 3: V920 v Cohort 3: Placebo v Cohort 4: V920 v Cohort 4: Placebo v Cohort 5: V920 v Cohort 5: Placebo
Number of subjects included in analysis	250
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA
Parameter estimate	Fold difference
Point estimate	42.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.49
upper limit	58.43

Primary: Geometric Mean Titers Induced by V920 in Cohort 5

End point title	Geometric Mean Titers Induced by V920 in Cohort 5[5]

End point description:

Geometric Mean Titers (GMTs) for ZEBOV-specific antibodies at Day 28 were calculated for each treatment group, along with two-sided 95% CIs, by exponentiating the corresponding log-transformed mean and two-sided 95% confidence limits. Only Cohort 5 received 2 doses of vaccine.

End point type	Primary

End point timeframe:

28 days after LAST (second) dose of vaccine

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: Analyses for this endpoint included only Cohort 5 (the Cohort that received 2 doses of study product).

End point values	Cohort 5: V920	Cohort 5: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	10		
Units: Titer				
geometric mean (confidence interval 95%)	8416.0 (6461.9 to 10961.1)	40.3 (23.8 to 68.4)		

Statistical analyses

Statistical analysis title	GMTs for ZEBOV-specific antibodies (Cohort 5)

Statistical analysis description:

Geometric Mean Titers (GMTs) for ZEBOV-specific antibodies at Day 28 following the second vaccination (day 84 post-vaccination 1) were calculated for each treatment group in cohort 5, along with two-sided 95% CIs. Mean fold difference between treatment groups was compared using ANOVA.

Comparison groups	Cohort 5: V920 v Cohort 5: Placebo
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA
Parameter estimate	Fold difference
Point estimate	208.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	115.57
upper limit	376.72

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events reported in this section are collected through 1-year post-vaccination.

Non-serious Adverse Events reported in this section are collected through 42 days post-vaccination.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Cohort 1: V920

Reporting group description:

Adults with screening CD4 cells/mm3 ≥ 500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Reporting group title	Cohort 1: Placebo

Reporting group description:

Adults with screening CD4 cells/mm3 ≥500 randomly assigned to receive placebo.

Reporting group title	Cohort 2: V920

Reporting group description:

Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Reporting group title	Cohort 2: Placebo

Reporting group description:

Adults with screening CD4 cells/mm3 >350 and <500 randomly assigned to receive placebo.

Reporting group title	Cohort 3: V920

Reporting group description:

Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Reporting group title	Cohort 3: Placebo

Reporting group description:

Adults with screening CD4 cells/mm3 ≥200 and ≤350 randomly assigned to receive placebo.

Reporting group title	Cohort 4: V920

Reporting group description:

Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine.

Reporting group title	Cohort 4: Placebo

Reporting group description:

Adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo.

Reporting group title	Cohort 5: V920

Reporting group description:

Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive ≥2 x 107 pfu of the V920 (rVSVΔG-ZEBOV-GP) Ebola Virus Vaccine. This cohort received 2 doses 56 days apart.

Reporting group title	Cohort 5: Placebo

Reporting group description:

Adults and adolescents with screening CD4 cells/mm3 ≥200 randomly assigned to receive placebo. This cohort received 2 doses 56 days apart.

Serious adverse events	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 10 (0.00%)	0 / 40 (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
Hepatobiliary disorders			
Hepatitis toxic			
subjects affected / exposed	1 / 40 (2.50%)	0 / 10 (0.00%)	0 / 40 (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
Musculoskeletal and connective tissue disorders			
Pseudarthrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	1 / 40 (2.50%)	0 / 10 (0.00%)	0 / 40 (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
Malaria			

subjects affected / exposed	1 / 40 (2.50%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2: Placebo	Cohort 3: V920	Cohort 3: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	1 / 41 (2.44%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 10 (0.00%)	1 / 41 (2.44%)	0 / 9 (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
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)	1 / 41 (2.44%)	0 / 9 (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
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis toxic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pseudarthrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			

subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 4: V920	Cohort 4: Placebo	Cohort 5: V920
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (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
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis toxic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Pseudarthrosis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 5: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatitis toxic			

subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Pseudarthrosis			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaria			
subjects affected / exposed	0 / 10 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Cohort 1: V920	Cohort 1: Placebo	Cohort 2: V920
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 40 (62.50%)	5 / 10 (50.00%)	11 / 40 (27.50%)
Injury, poisoning and procedural complications			
Limb injury	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Diastolic hypertension	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cervicobrachial syndrome	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		

subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Sciatica	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Dizziness	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	4 / 40 (10.00%)
occurrences (all)	0	0	4
Headache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	3 / 40 (7.50%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Diarrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	4 / 40 (10.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	4	0	0
Fatigue	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	6 / 40 (15.00%)	2 / 10 (20.00%)	0 / 40 (0.00%)
occurrences (all)	6	2	0
Pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Ill-defined disorder	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Toothache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Gastroenteritis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		

subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Bronchopneumopathy	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	3 / 40 (7.50%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	3	1	0
Psychiatric disorders			
Insomnia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Myalgia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Back pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Malaria	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	5 / 40 (12.50%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	5	1	0
Nasopharyngitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		

subjects affected / exposed	3 / 40 (7.50%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	3	1	0
Bronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Influenza	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Rhinitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sinobronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Otitis media chronic	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Cohort 2: Placebo	Cohort 3: V920	Cohort 3: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)	8 / 41 (19.51%)	5 / 9 (55.56%)
Injury, poisoning and procedural complications			
Limb injury	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Diastolic hypertension	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Cervicobrachial syndrome	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Diarrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Ill-defined disorder	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Toothache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Non-serious Adverse Events through to 42 days post-		

	vaccination		
subjects affected / exposed	1 / 10 (10.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Abdominal pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Bronchopneumopathy	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			

Malaria	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Influenza	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	4 / 41 (9.76%)	1 / 9 (11.11%)
occurrences (all)	0	4	1
Sinobronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	4 / 41 (9.76%)	1 / 9 (11.11%)
occurrences (all)	0	3	1
Otitis media chronic	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)	0 / 41 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 4: V920	Cohort 4: Placebo	Cohort 5: V920
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 40 (50.00%)	4 / 10 (40.00%)	13 / 40 (32.50%)
Injury, poisoning and procedural complications			

Limb injury	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	2 / 40 (5.00%)
occurrences (all)	0	0	2
Vascular disorders			
Diastolic hypertension	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Cervicobrachial syndrome	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Sciatica	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Dizziness	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Headache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	3 / 40 (7.50%)
occurrences (all)	0	1	3
General disorders and administration site conditions			
Diarrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Fatigue	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Ill-defined disorder	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			

Toothache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Abdominal pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Dysmenorrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	5 / 40 (12.50%)	1 / 10 (10.00%)	3 / 40 (7.50%)
occurrences (all)	5	1	3
Bronchopneumopathy	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Back pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		

subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Malaria	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	4 / 40 (10.00%)	1 / 10 (10.00%)	2 / 40 (5.00%)
occurrences (all)	4	1	2
Nasopharyngitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Bronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Conjunctivitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	2	0	0
Influenza	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0
Rhinitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	2 / 40 (5.00%)	0 / 10 (0.00%)	3 / 40 (7.50%)
occurrences (all)	2	0	3
Sinobronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	3 / 40 (7.50%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	3	0	0
Otitis media chronic	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	1 / 10 (10.00%)	0 / 40 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 40 (0.00%)	0 / 10 (0.00%)	0 / 40 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 5: Placebo		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	4 / 10 (40.00%)		
Injury, poisoning and procedural complications			
Limb injury	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Diastolic hypertension	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Cervicobrachial syndrome	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sciatica	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Dizziness	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Headache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Diarrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Fatigue	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Ill-defined disorder	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		

subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Toothache	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Gastroenteritis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Abdominal pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Bronchopneumopathy	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Psychiatric disorders			
Insomnia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

Myalgia	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Back pain	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Malaria	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Nasopharyngitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Bronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Conjunctivitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Influenza	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Rhinitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Sinobronchitis	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Otitis media chronic	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			

Decreased appetite	Additional description: Non-serious Adverse Events through to 42 days post-vaccination		
subjects affected / exposed	0 / 10 (0.00%)		
occurrences (all)	0		

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