Clinical trial results:
A Randomized, Observer-blind, Placebo-controlled, Phase 2 Study to Evaluate the Safety, Tolerability and Immunogenicity of Three Prime-boost Regimens of the Candidate Prophylactic Vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo in Healthy Adults in Europe

Summary

EudraCT number	2015-000596-27
Trial protocol	GB
Global end of trial date	19 January 2018

Results information

Result version number	v2 (current)
This version publication date	25 September 2019
First version publication date	03 February 2019
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	VAC52150EBL2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02416453
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Vaccines & Prevention B.V.
Sponsor organisation address	Archimedesweg 4-6, Leiden, Netherlands, 2333 CN
Public contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Vaccines & Prevention B.V., ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 November 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 January 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the safety and tolerability of 3 vaccination schedules of Ad26 vector expressing the glycoprotein of the Ebola virus Mayinga variant (Ad26.ZEBOV) and Modified Vaccinia Ankara - Bavarian Nordic vector expressing the glycoproteins of Ebola virus, Sudan virus and Marburg virus and the nucleoprotein of Tai Forest virus (MVA-BN-Filo) administered intramuscularly (IM) as heterologous 2-dose regimens on Days 1 and 29, Days 1 and 57, or Days 1 and 85 (Groups 1 to 3).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. Safety evaluations included measurement of vital signs, clinical laboratory tests (Hematology, serum chemistry and urinalysis), assessment of adverse events (AEs) including reactogenicity, physical examinations, and electrocardiograms (ECG).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 June 2015
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 197
Country: Number of subjects enrolled	United Kingdom: 224
Worldwide total number of subjects	421
EEA total number of subjects	421

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	418
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 421 subjects were enrolled and treated. Of the 421 subjects, 406 subjects were enrolled in groups 1 to 3 (30 subjects in cohort I, 376 subjects in cohort II & III) and 15 subjects in group 4.

Period 1

Period 1 title	REGIMEN (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	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval

Arm description:

Subjects received intramuscular (IM) injection of Ad26 vector expressing the glycoprotein of the Ebola virus Mayinga variant (Ad26.ZEBOV) at a dose of 5*10^10 viral particles (vp) as Dose 1 on Day 1, followed by Modified Vaccinia Ankara - Bavarian Nordic vector expressing the glycoproteins of Ebola virus, Sudan virus and Marburg virus and the nucleoprotein of Tai Forest virus (MVA-BN-Filo) at a dose of 1*10^8 infectious units (Inf.U) (nominal titer) as Dose 2 on Day 29 in an open-label fashion.

Arm type	Experimental
Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29.

Arm title	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in an open-label fashion.

Arm type	Experimental
Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Arm title	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in an open-label fashion.

Arm type	Experimental
Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Arm title	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29 in a blinded fashion.

Arm type	Experimental
Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Arm title	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval

Arm description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 29 in a blinded fashion.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 29.

Arm title	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in a blinded fashion.

Arm type	Experimental
Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57.

Arm title	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval

Arm description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 57 in a blinded fashion.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 57.

Arm title	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in a blinded fashion.

Arm type	Experimental

Investigational medicinal product name	MVA-BN-Filo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85.

Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Arm title	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval

Arm description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 85 in a blinded fashion.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 85.

Arm title	Group 4: Ad26.ZEBOV

Arm description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1 in a blinded fashion.

Arm type	Experimental
Investigational medicinal product name	Ad26.ZEBOV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1.

Arm title	Group 4: Placebo

Arm description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1 in a blinded fashion.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1.

Number of subjects in period 1	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Started	10	10	10
Completed	7	7	9
Not completed	3	3	1
Consent withdrawn by subject	2	-	-
Physician decision	-	-	-
Adverse event, non-fatal	-	-	-
Other	-	-	1
Lost to follow-up	1	3	-

Number of subjects in period 1	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Started	112	13	114
Completed	97	12	98
Not completed	15	1	16
Consent withdrawn by subject	5	1	8
Physician decision	-	-	1
Adverse event, non-fatal	2	-	1
Other	-	-	1
Lost to follow-up	8	-	5

Number of subjects in period 1	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Started	13	106	18
Completed	11	94	13
Not completed	2	12	5
Consent withdrawn by subject	-	8	4
Physician decision	1	1	-
Adverse event, non-fatal	-	-	-
Other	-	-	-
Lost to follow-up	1	3	1

Number of subjects in period 1	Group 4: Ad26.ZEBOV	Group 4: Placebo
Started	13	2
Completed	13	2
Not completed	0	0
Consent withdrawn by subject	-	-

Physician decision	-	-
Adverse event, non-fatal	-	-
Other	-	-
Lost to follow-up	-	-

Baseline characteristics

Reporting groups

Reporting group title	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval
Reporting group description:	
Subjects received intramuscular (IM) injection of Ad26 vector expressing the glycoprotein of the Ebola virus Mayinga variant (Ad26.ZEBOV) at a dose of 5*10^10 viral particles (vp) as Dose 1 on Day 1, followed by Modified Vaccinia Ankara - Bavarian Nordic vector expressing the glycoproteins of Ebola virus, Sudan virus and Marburg virus and the nucleoprotein of Tai Forest virus (MVA-BN-Filo) at a dose of 1*10^8 infectious units (Inf.U) (nominal titer) as Dose 2 on Day 29 in an open-label fashion.	
Reporting group title	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in an open-label fashion.	
Reporting group title	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in an open-label fashion.	
Reporting group title	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29 in a blinded fashion.	
Reporting group title	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 29 in a blinded fashion.	
Reporting group title	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in a blinded fashion.	
Reporting group title	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 57 in a blinded fashion.	
Reporting group title	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in a blinded fashion.	
Reporting group title	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 85 in a blinded fashion.	
Reporting group title	Group 4: Ad26.ZEBOV
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1 in a blinded fashion.	
Reporting group title	Group 4: Placebo
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1 in a blinded fashion.	

Reporting group values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Number of subjects	10	10	10
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	10	10	10
From 65 to 84 years	0	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	34.2	47.4	38.7
standard deviation	± 12.95	± 16.53	± 13.99
Title for Gender Units: subjects			
Female	4	6	7
Male	6	4	3

Reporting group values	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Number of subjects	112	13	114
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	111	13	114
From 65 to 84 years	1	0	0
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	41	39.1	41
standard deviation	± 15	± 13.9	± 14.02
Title for Gender Units: subjects			
Female	57	6	62
Male	55	7	52

Reporting group values	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Number of subjects	13	106	18
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	13	104	18

From 65 to 84 years	0	2	0
85 years and over	0	0	0

Title for AgeContinuous			
Units: years			
arithmetic mean	38.2	38.3	41.1
standard deviation	± 13.66	± 14.34	± 15.11
Title for Gender			
Units: subjects			
Female	8	53	10
Male	5	53	8

Reporting group values	Group 4: Ad26.ZEBOV	Group 4: Placebo	Total
Number of subjects	13	2	421
Title for AgeCategorical			
Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	13	2	418
From 65 to 84 years	0	0	3
85 years and over	0	0	0
Title for AgeContinuous			
Units: years			
arithmetic mean	37.9	47	
standard deviation	± 11.37	± 4.24	-
Title for Gender			
Units: subjects			
Female	3	1	217
Male	10	1	204

End points

End points reporting groups

Reporting group title	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval
Reporting group description:	
Subjects received intramuscular (IM) injection of Ad26 vector expressing the glycoprotein of the Ebola virus Mayinga variant (Ad26.ZEBOV) at a dose of 5*10^10 viral particles (vp) as Dose 1 on Day 1, followed by Modified Vaccinia Ankara - Bavarian Nordic vector expressing the glycoproteins of Ebola virus, Sudan virus and Marburg virus and the nucleoprotein of Tai Forest virus (MVA-BN-Filo) at a dose of 1*10^8 infectious units (Inf.U) (nominal titer) as Dose 2 on Day 29 in an open-label fashion.	
Reporting group title	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in an open-label fashion.	
Reporting group title	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in an open-label fashion.	
Reporting group title	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29 in a blinded fashion.	
Reporting group title	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 29 in a blinded fashion.	
Reporting group title	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in a blinded fashion.	
Reporting group title	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 57 in a blinded fashion.	
Reporting group title	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by of MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in a blinded fashion.	
Reporting group title	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 85 in a blinded fashion.	
Reporting group title	Group 4: Ad26.ZEBOV
Reporting group description:	
Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1 in a blinded fashion.	
Reporting group title	Group 4: Placebo
Reporting group description:	
Subjects received Placebo (0.9% saline) as Dose 1 on Day 1 in a blinded fashion.	

Primary: Group 1, 2 and 3: Percentage of Subjects with Adverse Events (Unsolicited Adverse Events)

End point title	Group 1, 2 and 3: Percentage of Subjects with Adverse Events (Unsolicited Adverse Events)[1][2]

End point description:

An adverse event (AE) is any untoward medical occurrence in a clinical study subject administered a medicinal product, it does not necessarily have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal product. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Primary

End point timeframe:

From signing of ICF (Inform Consent Form) Up to 42-day post-dose 2 visit (Day 71 for Group 1; Day 99 for Group 2; and Day 127 for Group 3)

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: Descriptive statistics were done, no inferential statistical analyses were performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be reported for the specified arms only.

End point values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	112
Units: Percentage of subjects				
number (not applicable)	40.0	60.0	60.0	55.4

End point values	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	114	13	106
Units: Percentage of subjects				
number (not applicable)	46.2	45.6	53.8	43.4

End point values	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval			

Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (not applicable)	44.4			

Statistical analyses

No statistical analyses for this end point

Primary: Group 1, 2 and 3: Percentage of Subjects with Serious Adverse Events (SAEs)

End point title	Group 1, 2 and 3: Percentage of Subjects with Serious Adverse Events (SAEs)[3][4]

End point description:

SAEs are any untoward medical occurrence that at any dose results in death, is life-threatening (the subject was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe), requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Primary

End point timeframe:

From signing of ICF up to end of the study (Day 365)

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: Descriptive statistics were done, no inferential statistical analyses were performed.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be reported for the specified arms only.

End point values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	112
Units: Percentage of subjects				
number (not applicable)	0	10.0	0	1.8

End point values	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	114	13	106
Units: Percentage of subjects				

number (not applicable)	0	3.5	7.7	4.7

End point values	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (not applicable)	5.6			

Statistical analyses

No statistical analyses for this end point

Primary: Group 1, 2 and 3: Percentage of Subjects with Immediate Reportable Events (IREs)

End point title	Group 1, 2 and 3: Percentage of Subjects with Immediate Reportable Events (IREs)[5][6]

End point description:

Any event of neuroimmunologic significance categorized as IREs which includes Cranial nerve disorders, including Paralyses/paresis, Optic neuritis, Multiple sclerosis, Transverse myelitis, Guillain-Barre syndrome, Miller Fisher syndrome, Bickerstaff's encephalitis, Acute disseminated encephalomyelitis (including site specific variants: non-infectious encephalitis, encephalomyelitis, myelitis, myeloradiculomyelitis), Myasthenia gravis, Lambert-Eaton myasthenic syndrome, Immune-mediated peripheral neuropathies, plexopathies (including chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy and polyneuropathies associated with monoclonal gammopathy), Narcolepsy, Isolated paresthesia of greater than (>) 7 days duration. Full Analysis set included all subjects who were randomized, received at least one dose of study vaccine, regardless of the occurrence of protocol deviations. Here, '99999' defines that no immediate reportable events indicated for cohort 1.

End point type	Primary

End point timeframe:

From signing of ICF Up to end of the study (Day 365)

Notes:

[5] - 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: Descriptive statistics were done, no inferential statistical analyses were performed.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be reported for the specified arms only.

End point values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	112
Units: Percentage of subjects				
number (not applicable)	99999	99999	99999	0

End point values	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	114	13	106
Units: Percentage of subjects				
number (not applicable)	0	1.8	0	1.9

End point values	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Group 1, 2 and 3: Percentage of Subjects with Solicited Local Adverse Events

End point title	Group 1, 2 and 3: Percentage of Subjects with Solicited Local Adverse Events[7][8]

End point description:

Subjects with solicited local (injection site) adverse events were instructed on how to note occurrences of erythema, induration/swelling (measured using the ruler supplied), pain/tenderness and itching at the injection site in the evening after each study vaccine administration and then daily for the next 7 days in the diary. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations. Here 'n' indicates the number of subjects who were analyzed at specified timepoint for each arm.

End point type	Primary

End point timeframe:

Up to 7 days Post Dose 1 (Day 8 for Group 1, 2 and 3) and Post Dose 2 (Day 35, 63 and 91 for Group 1, 2 and 3 respectively)

Notes:

[7] - 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: Descriptive statistics were done, no inferential statistical analyses were performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoint was planned to be reported for the specified arms only.

End point values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	112
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13, 114,13,106,18)	80.0	60.0	80.0	56.3
Post-dose 2(n=8,9,9, 91,10,83,7,62,11)	50.0	55.6	88.9	50.5

End point values	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	114	13	106
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13, 114,13,106,18)	23.1	57.0	15.4	73.6
Post-dose 2(n=8,9,9, 91,10,83,7,62,11)	20.0	59.0	0	66.1

End point values	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13, 114,13,106,18)	22.2			
Post-dose 2(n=8,9,9, 91,10,83,7,62,11)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Group 1, 2 and 3: Percentage of Subjects with Solicited Systemic Adverse Events

End point title	Group 1, 2 and 3: Percentage of Subjects with Solicited Systemic Adverse Events[9][10]

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal product. Solicited systemic AEs included fever (defined as body temperature of 38 degree Celsius or higher), Headache, fatigue/Malaise, myalgia, nausea/vomiting, arthralgia, chills. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations. Here 'n' signifies number of subjects who were analyzed at specified timepoint for each arm.

End point type	Primary

End point timeframe:

Up to 7 days Post Dose 1 (Day 8 for Group 1, 2 and 3) and Post Dose 2 (Day 35, 63 and 91 for Group 1, 2 and 3 respectively)

Notes:

[9] - 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: Descriptive statistics were done, no inferential statistical analyses were performed.

[10] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group1: Cohort I: Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	112
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13,114,13,106,18)	80.0	100.0	100.0	79.5
Post-dose 2 (n=8,9,9,91,10,83,7,62,11)	75.0	55.6	55.6	46.2

End point values	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	114	13	106
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13,114,13,106,18)	53.8	73.7	61.5	77.4
Post-dose 2 (n=8,9,9,91,10,83,7,62,11)	50.0	43.4	28.6	61.3

End point values	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval			

Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage of subjects				
number (not applicable)				
Post-dose 1 (n=10,10,10,112,13,114,13,106,18)	38.9			
Post-dose 2 (n=8,9,9,91,10,83,7,62,11)	36.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Group 4: Percentage of Subjects with Adverse Events (Unsolicited Adverse Events)

End point title	Group 4: Percentage of Subjects with Adverse Events (Unsolicited Adverse Events)[11]

End point description:

An AE is any untoward medical occurrence in a clinical study subject administered a medicinal product, it does not necessarily have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal product. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Secondary

End point timeframe:

Up to 28-day post vaccination visit (Day 29 for Group 4)

Notes:

[11] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group 4: Ad26.ZEBOV	Group 4: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	2		
Units: Percentage of subjects				
number (not applicable)	46.2	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 4: Percentage of Subjects with Serious Adverse Events

End point title	Group 4: Percentage of Subjects with Serious Adverse

End point description:

SAEs are any untoward medical occurrence that at any dose results in death, is life-threatening (the subject was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe), requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital

anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product. Full Analysis set includes all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Secondary

End point timeframe:

From signing of ICF up to end of the study (Day 365)

Notes:

[12] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group 4: Ad26.ZEBOV	Group 4: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	2		
Units: Percentage of subjects				
number (not applicable)	15.4	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 4: Percentage of Subjects with Immediate Reportable Events (IREs)

End point title	Group 4: Percentage of Subjects with Immediate Reportable Events (IREs)[13]

End point description:

Any event of neuroimmunologic significance categorized as IREs which includes Cranial nerve disorders, including Paralyses/paresis, Optic neuritis, Multiple sclerosis, Transverse myelitis, Guillain-Barre syndrome, including Miller Fisher syndrome, Bickerstaff's encephalitis, Acute disseminated encephalomyelitis (including site specific variants: non-infectious encephalitis, encephalomyelitis, myelitis, myeloradiculomyelitis), Myasthenia gravis and Lambert-Eaton myasthenic syndrome, Immune-mediated peripheral neuropathies and plexopathies (including chronic inflammatory demyelinating polyneuropathy, multifocal motor neuropathy and polyneuropathies associated with monoclonal gammopathy), Narcolepsy, Isolated paresthesia of >7 days duration. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations. Here, '99999' defines that no immediate reportable events indicated for Group 4.

End point type	Secondary

End point timeframe:

From signing of ICF up to end of the study (Day 365)

Notes:

[13] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group 4: Ad26.ZEBOV	Group 4: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	2		
Units: Percentage of subjects				
number (not applicable)	99999	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 4: Percentage of Subjects with Solicited Local Adverse Events

End point title	Group 4: Percentage of Subjects with Solicited Local Adverse Events[14]

End point description:

Solicited adverse events are precisely defined events that subjects are specifically asked about and which are noted by subjects in the diary. Subjects with Solicited Local (Injection Site) Adverse Events were instructed on how to note occurrences of erythema, induration/swelling (measured using the ruler supplied), pain/tenderness and itching at the injection site in the evening after each study vaccine administration and then daily for the next 7 days in the diary. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Secondary

End point timeframe:

Up to 7 days Post-dose 1 (Day 8)

Notes:

[14] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group 4: Ad26.ZEBOV	Group 4: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	2		
Units: Percentage of subjects				
number (not applicable)	61.5	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 4: Percentage of Subjects with Solicited Systemic Adverse Events

End point title	Group 4: Percentage of Subjects with Solicited Systemic Adverse Events[15]

End point description:

An AE is defined as any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non-investigational) product, whether or not related to that medicinal product. Solicited systemic AEs included fever (defined as body temperature of 38°C or higher), Headache, fatigue/Malaise, myalgia, nausea/vomiting, arthralgia, chills. Full Analysis set included all subjects who were randomized and received at least one dose of study vaccine, regardless of the occurrence of protocol deviations.

End point type	Secondary

End point timeframe:

Up to 7 days Post-dose 1 (Day 8)

Notes:

[15] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group 4: Ad26.ZEBOV	Group 4: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	2		
Units: Percentage of subjects				
number (not applicable)	84.6	50.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Anti-Ebola Virus (EBOV) Glycoprotein (GP) Binding Antibody Responses

End point title	Percentage of Subjects with Anti-Ebola Virus (EBOV) Glycoprotein (GP) Binding Antibody Responses[16]

End point description:

Humoral immune responses were measured by binding antibody responses using EBOV GP Filovirus Animal Nonclinical Group (FANG) enzyme-linked immunosorbent assay (ELISA). The per Protocol analysis set included all randomized and vaccinated subjects, who received both the dose 1 and dose 2 (administered not more than 10 days outside the visit window) vaccinations, had immunogenicity data from baseline and at least one post-vaccination evaluable immunogenicity sample, and had no major protocol violations influencing the immune response. Here, 99999 indicates that data was not reported as no subjects analyzed in the respective group at specified timepoint. Here 'N' (number of subjects analyzed) signifies number of subjects evaluable for this endpoint and 'n' indicates the number of subjects who were analyzed at specified timepoint for each arm.

End point type	Secondary

End point timeframe:

At 21 days post Dose 2 (Day 50 for Group 1; Day 78 for Group 2; and Day 106 for Group 3)

Notes:

[16] - 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: Endpoint was planned to be reported for the specified arms only.

End point values	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	8	70	7
Units: Percentage of subjects				
number (not applicable)				
Day 50 (n=77, 7, 0, 0, 0, 0)	98.7	0	99999	99999
Day 78 (n=0, 0, 69, 7, 0, 0)	99999	99999	100	0
Day 106 (n=0, 0, 0, 0, 48, 6)	99999	99999	99999	99999

End point values	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	6		
Units: Percentage of subjects				
number (not applicable)				
Day 50 (n=77, 7, 0, 0, 0, 0)	99999	99999		
Day 78 (n=0, 0, 69, 7, 0, 0)	99999	99999		
Day 106 (n=0, 0, 0, 0, 48, 6)	100	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Screening up to Day 365

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Group1:Cohort I:Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval

Reporting group description:

Subjects received intramuscular (IM) injection of Ad26 vector expressing the glycoprotein of the Ebola virus Mayinga variant (Ad26.ZEBOV) at a dose of 5*10^10 viral particles (vp) as Dose 1 on Day 1, followed by Modified Vaccinia Ankara – Bavarian Nordic vector expressing the glycoproteins of Ebola virus, Sudan virus and Marburg virus and the nucleoprotein of Tai Forest virus (MVA-BN-Filo) at a dose of 1*10^8 infectious units (Inf.U) (nominal titer) as Dose 2 on Day 29 in an open-label fashion.

Reporting group title	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in an open-label fashion.

Reporting group title	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in an open-label fashion.

Reporting group title	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 29 in a blinded fashion.

Reporting group title	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval

Reporting group description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 29 in a blinded fashion.

Reporting group title	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 57 in a blinded fashion.

Reporting group title	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval

Reporting group description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 56 in a blinded fashion.

Reporting group title	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1, followed by MVA-BN-Filo at a dose of 1*10^8 Inf.U (nominal titer) as Dose 2 on Day 85 in a blinded fashion.

Reporting group title	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval

Reporting group description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1, followed by placebo (0.9% saline) as Dose 2 on Day 85 in a blinded fashion.

Reporting group title	Group 4: Ad26

Reporting group description:

Subjects received IM injection of Ad26.ZEBOV at a dose of 5*10^10 vp as Dose 1 on Day 1 in a blinded fashion.

Reporting group title	Group 4: Placebo

Reporting group description:

Subjects received Placebo (0.9% saline) as Dose 1 on Day 1 in a blinded fashion.

Serious adverse events	Group1:Cohort I:Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteosarcoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Breast Cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Investigations			
Human Papilloma Virus Test Positive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Nervous system disorders			
Miller Fisher Syndrome			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Small Fibre Neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Cerebral Venous Thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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			
Cholecystitis Acute			

subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Hepatitis A			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (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	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 112 (1.79%)	0 / 13 (0.00%)	4 / 114 (3.51%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteosarcoma			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Breast Cancer			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (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
Investigations			
Human Papilloma Virus Test Positive			

subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Miller Fisher Syndrome			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Fibre Neuropathy			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Cerebral Venous Thrombosis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Gastrointestinal disorders			
Inguinal Hernia			

subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Haemorrhoids			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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			
Cholecystitis Acute			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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			
Cellulitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (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
Chronic Sinusitis			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (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
Hepatitis A			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)	5 / 106 (4.72%)	1 / 18 (5.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteosarcoma			

subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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
Investigations			
Human Papilloma Virus Test Positive			
subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	0 / 18 (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
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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
Nervous system disorders			
Miller Fisher Syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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
Small Fibre Neuropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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
Cerebral Venous Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			

subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (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
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (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			
Inguinal Hernia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (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
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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			
Cholecystitis Acute			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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			
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (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
Chronic Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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
Hepatitis A			

subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (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	Group 4: Ad26	Group 4: Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 13 (15.38%)	0 / 2 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Osteosarcoma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast Cancer			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Human Papilloma Virus Test Positive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Appendicectomy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Miller Fisher Syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small Fibre Neuropathy			

subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral Venous Thrombosis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Food Allergy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Inguinal Hernia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis Acute			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic Sinusitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis A			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group1:Cohort I:Ad26.ZEBOV then MVA-BN-Filo,28-Day Interval	Group 2:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 56-Day Interval	Group 3:Cohort I: Ad26.ZEBOV then MVA-BN-Filo, 84-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)	5 / 10 (50.00%)	6 / 10 (60.00%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Neutrophil Count Decreased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	2 / 10 (20.00%)
occurrences (all)	1	1	3
Prothrombin Time Prolonged			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Ligament Sprain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Application Site Bruise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Influenza Like Illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Injection Site Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dental Discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 10 (20.00%)
occurrences (all)	0	0	2
Odynophagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oral Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Chondropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 10 (10.00%)	1 / 10 (10.00%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Tooth Abscess			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Urinary Tract Infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group1:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,28-Day Interval	Group 1: Cohorts II & III: Placebo, Placebo, 28-Day Interval	Group2:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,56-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 112 (36.61%)	6 / 13 (46.15%)	30 / 114 (26.32%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	0	0	1
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	3 / 114 (2.63%)
occurrences (all)	0	0	3
Blood Creatinine Increased			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	1	0	0
Neutrophil Count Decreased			
subjects affected / exposed	3 / 112 (2.68%)	0 / 13 (0.00%)	2 / 114 (1.75%)
occurrences (all)	3	0	2
Prothrombin Time Prolonged			

subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Ligament Sprain			
subjects affected / exposed	1 / 112 (0.89%)	1 / 13 (7.69%)	0 / 114 (0.00%)
occurrences (all)	2	1	0
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 112 (2.68%)	1 / 13 (7.69%)	3 / 114 (2.63%)
occurrences (all)	3	1	3
General disorders and administration site conditions			
Application Site Bruise			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	0	0	1
Influenza Like Illness			
subjects affected / exposed	2 / 112 (1.79%)	0 / 13 (0.00%)	2 / 114 (1.75%)
occurrences (all)	2	0	2
Injection Site Erythema			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	1	0	0
Injection Site Pain			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 112 (0.00%)	1 / 13 (7.69%)	1 / 114 (0.88%)
occurrences (all)	0	1	1
Gastrointestinal disorders			
Dental Discomfort			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	2 / 114 (1.75%)
occurrences (all)	0	0	2
Odynophagia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Oral Pain			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	2 / 112 (1.79%)	0 / 13 (0.00%)	2 / 114 (1.75%)
occurrences (all)	2	0	2
Rhinorrhoea			
subjects affected / exposed	4 / 112 (3.57%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	4	0	1
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	1	0	1
Back Pain			
subjects affected / exposed	3 / 112 (2.68%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	4	0	2
Chondropathy			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	2 / 112 (1.79%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	2	0	0
Osteoarthritis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	1 / 112 (0.89%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	1	0	1
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 13 (7.69%)	0 / 114 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			

subjects affected / exposed	3 / 112 (2.68%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	3	0	0
Pharyngitis			
subjects affected / exposed	2 / 112 (1.79%)	0 / 13 (0.00%)	0 / 114 (0.00%)
occurrences (all)	3	0	0
Rhinitis			
subjects affected / exposed	7 / 112 (6.25%)	0 / 13 (0.00%)	6 / 114 (5.26%)
occurrences (all)	8	0	6
Tooth Abscess			
subjects affected / exposed	0 / 112 (0.00%)	0 / 13 (0.00%)	1 / 114 (0.88%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	6 / 112 (5.36%)	1 / 13 (7.69%)	6 / 114 (5.26%)
occurrences (all)	7	1	6
Urinary Tract Infection			
subjects affected / exposed	1 / 112 (0.89%)	1 / 13 (7.69%)	0 / 114 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Group 2: Cohorts II & III: Placebo, Placebo, 56-Day Interval	Group3:Cohorts II & III:Ad26.ZEBOV/MVA-BN-Filo,84-Day Interval	Group 3: Cohorts II & III: Placebo, Placebo, 84-Day Interval
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 13 (53.85%)	26 / 106 (24.53%)	8 / 18 (44.44%)
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 13 (0.00%)	3 / 106 (2.83%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 13 (0.00%)	3 / 106 (2.83%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Blood Creatinine Increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neutrophil Count Decreased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 106 (1.89%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Prothrombin Time Prolonged			

subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Ligament Sprain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Headache			
subjects affected / exposed	1 / 13 (7.69%)	5 / 106 (4.72%)	0 / 18 (0.00%)
occurrences (all)	1	12	0
General disorders and administration site conditions			
Application Site Bruise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Influenza Like Illness			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Injection Site Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Dental Discomfort			
subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	1 / 106 (0.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 13 (15.38%)	3 / 106 (2.83%)	0 / 18 (0.00%)
occurrences (all)	2	3	0
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Back Pain			
subjects affected / exposed	1 / 13 (7.69%)	3 / 106 (2.83%)	0 / 18 (0.00%)
occurrences (all)	1	3	0
Chondropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			

subjects affected / exposed	1 / 13 (7.69%)	1 / 106 (0.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	3 / 106 (2.83%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Tooth Abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 13 (7.69%)	3 / 106 (2.83%)	1 / 18 (5.56%)
occurrences (all)	1	3	1
Urinary Tract Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 106 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group 4: Ad26	Group 4: Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 13 (46.15%)	1 / 2 (50.00%)	
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Blood Creatinine Increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Neutrophil Count Decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Prothrombin Time Prolonged			

subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Ligament Sprain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Dizziness Postural			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Application Site Bruise			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Influenza Like Illness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Injection Site Erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Injection Site Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Dental Discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Odynophagia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Oral Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Back Pain			
subjects affected / exposed	2 / 13 (15.38%)	0 / 2 (0.00%)	
occurrences (all)	2	0	
Chondropathy			
subjects affected / exposed	0 / 13 (0.00%)	1 / 2 (50.00%)	
occurrences (all)	0	1	
Musculoskeletal Pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Osteoarthritis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 2 (0.00%)	
occurrences (all)	1	0	
Pain in Extremity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Tooth Abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	
Urinary Tract Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 2 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 May 2015	This amendment was created upon request of the Medicines and Healthcare Products Regulatory Agency (MHRA). Further modifications were made to implement a site-specific request, to update the list of references and to correct minor inconsistencies.
18 August 2015	This amendment was created to implement site-specific requests and only subjects who received active vaccine were entered a long-term follow-up phase.
26 January 2016	This amendment includes the request of the Center for Biologics Evaluation and Research (CBER, a division of US Food and Drug Administration [FDA]) to extend the safety follow-up to 6 months post-dose 2.
01 September 2016	The sponsor halted vaccinations following a case of Miller Fisher syndrome after receipt of MVA-BN-Filo or placebo in this clinical study, until a revised inform consent form (ICF) containing updated safety language for the current study VAC52150EBL2001 was prepared and approval to restart the study was granted by the relevant competent authority. As a result of the pause, some subjects were outside the protocol-defined dose 2 vaccination window. Information was added to clarify the procedures that need to be followed for these subjects. As requested by the Agence Nationale de Securite du Medicament et des produits de sante (ANSM), wording on the collection of Immediate Reportable Events was added after observation of the case of Miller Fisher syndrome. Randomization to Group 3 was stopped to focus on the schedules for which an indication was sought.
20 April 2017	This amendment was created due to significant delays in scheduled dose 2 vaccinations caused by study pauses required for safety evaluations. Since many subjects in France have had no dose 2 vaccination and many subjects in the United Kingdom (UK) have had a late dose 2 vaccination, it was very difficult to evaluate the planned dosing regimens. Therefore, no further subjects were recruited in the entire study (ie, UK and France). Vaccinated subjects in both countries were followed per protocol for safety.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
27 April 2016	Study vaccinations were halted due to the occurrence of a serious adverse event (Miller Fisher syndrome). The event was considered to be possibly related to study vaccination by the investigator and therefore met the pre-specified pausing rules installed for this study. Per IDMC recommendation, further investigations and analyses were performed, and all study vaccinations were halted until the safety language of the ICF was updated.	27 May 2016

20 May 2016	A second serious adverse event was reported (initially reported as 'possible cervical myelitis', ultimately diagnosed as small fiber neuropathy), which also was assessed as possibly related to study vaccination by the investigator and investigated and analyzed further. This event resulted in halt of screening and all study vaccinations.	27 September 2016

Notes:

Limitations and caveats

None reported