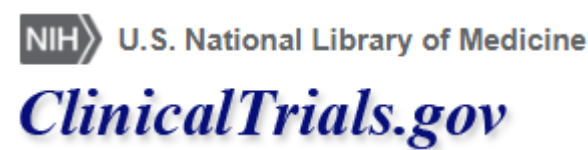


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A Non-inferiority Trial to Compare MVA-BN® Smallpox Vaccine to ACAM2000®

 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT01913353

[Recruitment Status](#) ⓘ : Completed
[First Posted](#) ⓘ : August 1, 2013
[Results First Posted](#) ⓘ : December 5, 2019
[Last Update Posted](#) ⓘ : December 5, 2019

Sponsor:

Bavarian Nordic

Collaborator:

US Army Medical Research Institute of Infectious Diseases

Information provided by (Responsible Party):

Bavarian Nordic

[Study Details](#)

[Tabular View](#)

[Study Results](#)

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Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Single (Outcomes Assessor); Primary Purpose: Prevention
Condition	18-42 Year Old Healthy Vaccinia-naïve Subjects

Interventions	Biological: MVA BN® Biological: ACAM2000®
Enrollment	440

Participant Flow Go to 

Recruitment Details		
Pre-assignment Details		
Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description	Two vaccinations; MVA BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA BN® vaccination (Day 56). MVA BN®: 0.5 ml MVA BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Period Title: Overall Study		
Started ^[1]	221	219
Completed ^[2]	189	204
Not Completed	32	15
<u>Reason Not Completed</u>		
Adverse Event	2	0
Physician Decision	0	2
Withdrawal by Subject	20	6
multiple reasons	10	7
^[1] Randomized including subjects not vaccinated		
^[2] Active trial phase		

Baseline Characteristics Go to 

Arm/Group Title	Group 1	Group 2	Total
▼ Arm/Group Description	Two vaccinations; MVA BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA BN® vaccination (Day 56). MVA BN®: 0.5 ml MVA BN® with a nominal titre of	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and	Total of all reporting groups

		1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	
Overall Number of Baseline Participants		220	213	433
▼ Baseline Analysis Population Description		Full Analysis Set		
Age, Continuous Mean (Standard Deviation) Unit of measure: Years				
	Number Analyzed	220 participants	213 participants	433 participants
		23.5 (4.77)	23.4 (4.58)	23.5 (4.67)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	220 participants	213 participants	433 participants
	Female	3917.7%	2913.6%	6815.7%
	Male	18182.3%	18486.4%	36584.3%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	220 participants	213 participants	433 participants
	Hispanic or Latino	5424.5%	4018.8%	9421.7%
	Not Hispanic or Latino	16675.5%	17381.2%	33978.3%
	Unknown or Not Reported	00.0%	00.0%	00.0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	220 participants	213 participants	433 participants

	American Indian or Alaska Native	8	3.6%	6	2.8%	14	3.2%
	Asian	14	6.4%	12	5.6%	26	6.0%
	Native Hawaiian or Other Pacific Islander	5	2.3%	3	1.4%	8	1.8%
	Black or African American	48	21.8%	40	18.8%	88	20.3%
	White	126	57.3%	136	63.8%	262	60.5%
	More than one race	0	0.0%	0	0.0%	0	0.0%
	Unknown or Not Reported	19	8.6%	16	7.5%	35	8.1%
Region of Enrollment Measure Type: Number Unit of measure: Participants							
South Korea	Number Analyzed	220 participants		213 participants		433 participants	
		220		213		433	

Outcome Measures ⓘ

Go to

1. Primary Outcome

Title	Plaque Reduction Neutralization Test (PRNT) Geometric Mean Titer (GMT) at the Peak Visits
▼ Description	GMT based on vaccinia-specific PRNT. Titers below the detection limit are included with a value of 1.
Time Frame	Day 42 for Group 1 and Day 28 for Group 2

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN [®] ; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000 [®] vaccine 4 weeks after the second MVA-BN [®] vaccination (Day 56). MVA-BN [®] : 0.5 ml MVA-BN [®] with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000 [®] will be administered at Day 0. ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Geometric Mean (95% Confidence Interval) Unit of Measure: Titer		
	153.5 (134.3 to 175.6)	79.3 (67.1 to 93.8)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Group 1, Group 2
	Comments	[Not Specified]
	Type of Statistical Test	Non-Inferiority
	Comments	The non-inferiority margin to show that Group 1 (after 2 doses of MVA-BN) is non-inferior to Group 2 (after 1 dose of ACAM2000) in terms of PRNT GMTs at the respective peak visit (Week 6 in Group 1 / Week 4 in Group 2) was predefined as '1/2 (i.e. 0.5)' for the GMT ratio (Group 1 / Group 2).
Method of Estimation	Estimation Parameter	GMT Ratio (Group 1 / Group 2)
	Estimated Value	1.935
	Confidence Interval	(2-Sided) 95% 1.562 to 2.397
	Estimation Comments	[Not Specified]

2. Primary Outcome

Title	Maximum Lesion Area (MLA) in mm2 After Scarification With ACAM2000®
▼ Description	The MLA was defined as the maximum of two measurements: the lesion area measured on Day 6-8 (after scarification) or the lesion area measured on Day 13-15 (after scarification). This was measured using the SilhouetteConnect camera system, and confirmed by the Independent Take Review Committee (ITRC).
Time Frame	Day 6-8, 13-15 after 3rd Vaccination for Group 1 and Day 6-8, 13-15 after 1st vaccination for Group 2

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm2		
	0.0 (0.0 to 2.0)	76.0 (70.0 to 87.0)

▼ Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Group 1, Group 2
	Comments	[Not Specified]
	Type of Statistical Test	Superiority
	Comments	Predefined threshold of clinical relevance for the area attenuation ratio (AAR): 40%
Method of Estimation	Estimation Parameter	Area attenuation ratio (AAR)
	Estimated Value	97.9
	Confidence Interval	(2-Sided) 95% 96.6 to 98.3
	Estimation Comments	The AAR, i.e. the reduction in MLA [1 - MLA ratio (Group 1/Group 2)] after scarification was to be significantly above 40%. The MLA ratio and the corresponding 95% CI were based on the Hodges-Lehmann estimate of the shift for log-transformed MLAs.

3. Secondary Outcome

Title	Investigator-measured Maximum Lesion Diameter (MLD) in mm After Scarification With ACAM2000
▼ Description	The MLD was defined as the largest major diameter measured across the lesion on Day 6-8 (after scarification) or Day 13-15 (after scarification)
Time Frame	Day 6-8 and Day 13-15 after ACAM2000 scarification

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm		
	0.0 (0.0 to 2.0)	11.0 (10.0 to 11.0)

4. Secondary Outcome

Title	Investigator-measured Lesion Diameter in mm at Day 6-8 After Scarification With ACAM2000
▼ Description	The lesion diameter at Day 6-8 was defined as the major lesion diameter measured on Day 6-8 (after scarification)
Time Frame	Day 6-8 after ACAM2000 scarification

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm		
	0.0 (0.0 to 2.0)	8.0 (8.0 to 9.0)

5. Secondary Outcome

Title	Investigator-measured Lesion Diameter in mm at Day 13-15 After Scarification With ACAM2000
▼ Description	The lesion diameter at Day 13-15 was defined as the major lesion diameter measured on Day 13-15 (after scarification)
Time Frame	Day 13-15 after ACAM2000 scarification

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm		
	0.0 (0.0 to 0.0)	10.0 (10.0 to 11.0)

6. Secondary Outcome

Title	Individual Take as Classified by a Blinded Independent Take Review Committee (ITRC)
▼ Description	Take was assessed as either full, partial, or absent take by the ITRC based on Day 6-8 evaluations following ACAM2000 vaccination using subject profiles that contained supportive data up to Day 14 following ACAM2000 vaccination (in accordance with the ITRC Charter).
Time Frame	Day 6-8 visit following ACAM2000 vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Measure Type: Number Number (95% Confidence Interval) Unit of Measure: percentage of subjects		
Full Take	23.0 (16.8 to 30.2)	92.5 (87.3 to 96.1)
Partial Take	23.0 (16.8 to 30.2)	4.3 (1.8 to 8.8)
Absent Take	53.9 (46.0 to 61.7)	1.9 (0.4 to 5.3)
Missing	0 (0.0 to 2.2)	1.2 (0.2 to 4.4)

7. Secondary Outcome

Title	Lesion Area in mm2 at Day 6-8 After Scarification With ACAM2000
▼ Description	Lesion area was measured by the Investigator using the SilhouetteConnect camera system and confirmed by the blinded ITRC.
Time Frame	Day 6-8 after ACAM2000 scarification

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN [®] ; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000 [®] vaccine 4 weeks after the second MVA-BN [®] vaccination (Day 56). MVA-BN [®] : 0.5 ml MVA-BN [®] with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000 [®] will be administered at Day 0. ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm2		
	0.0 (0.0 to 1.0)	37.0 (33.0 to 42.0)

8. Secondary Outcome

Title	Lesion Area in mm2 at Day 13-15 After Scarification With ACAM2000
▼ Description	Lesion area was measured by the Investigator using the SilhouetteConnect camera system and confirmed by the blinded ITRC.
Time Frame	Day 13-15 after ACAM2000 scarification

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	165	161
Median (95% Confidence Interval) Unit of Measure: mm2		
	0.0 (0.0 to 0.0)	75.0 (69.0 to 85.0)

9. Secondary Outcome

Title	Relationship to Vaccine of Any Serious Adverse Event (SAE)
▼ Description	Presentation of SAEs by relationship to study vaccine
Time Frame	Within 38 weeks for Group 1 and 30 weeks for Group 2

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	220	213
Measure Type: Number Unit of Measure: Events		
Unrelated/None	4	2
Unlikely	1	1
Possible	0	0
Probable	0	0
Definite	0	0

10. Secondary Outcome

Title	Intensity of Any Serious Adverse Event (SAE)
▼ Description	Presentation of SAEs by intensity
Time Frame	Within 38 weeks for Group 1 and 30 weeks for Group 2

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	220	213
Measure Type: Number Unit of Measure: participants		
Mild: routine daily activity not impaired	0	0
Moderate: routine daily activity impaired	0	0
Severe: prevents routine daily activities	1	1
Life threatening	4	2

11. Secondary Outcome

Title	Incidence of Any Cardiac Sign or Symptom Indicating a Case of Myo-/Pericarditis, i.e. Adverse Events of Special Interest (AESIs)
▼ Description	In this clinical trial, an AESI was defined as any cardiac sign or symptom developed since the first vaccination, any ECG changes determined to be clinically significant, or any cardiac enzyme results of Troponin I $\geq 2 \times$ ULN.
Time Frame	Within 38 weeks for Group 1 and 30 weeks for Group 2

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1	Group 1, Period 2	Group 1, Period 3	Group 2
▼ Arm/Group Description:	after 1st dose of MVA-BN	after second dose of MVA-BN	after ACAM2000	ACAM2000
Overall Number of Participants Analyzed	220	208	196	213
Measure Type: Count of Participants				
Unit of Measure: Participants				
	20.9%	21.0%	31.5%	41.9%

12. Secondary Outcome

Title	Related Grade ≥ 3 Adverse Events
▼ Description	Incidence of any Grade 3 or 4 adverse events (AEs) possibly, probably, or definitely related to the vaccine. Pooled solicited (general only) and unsolicited AEs.
Time Frame	within 29 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1	Group 1, Period 2	Group 1, Period 3	Group 2
▼ Arm/Group Description:	after 1st dose of MVA-BN	after 2nd dose of MVA-BN	after ACAM2000	ACAM2000
Overall Number of Participants Analyzed	220	208	196	213
Measure Type: Count of Participants				
Unit of Measure: Participants				
	31.4%	21.0%	31.5%	2210.3%

13. Secondary Outcome

Title	Relationship to Vaccine of Any Non-serious AEs
▼ Description	Presentation of non-serious AEs by relationship to study vaccine
Time Frame	within 29 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1	Group 1, Period 2	Group 1, Period 3	Group 2
▼ Arm/Group Description:	after 1st dose of MVA-BN	after 2nd dose of MVA-BN	after ACAM2000	ACAM2000
Overall Number of Participants Analyzed	220	208	196	213
Measure Type: Number Unit of Measure: Events				
Unrelated/None	94	67	110	102
Unlikely	24	19	29	23
Possible	27	15	18	30
Probable	5	1	0	6
Definite	107	56	9	34

14. Secondary Outcome

Title	Intensity of Any Non-serious AEs
▼ Description	Presentation of non-serious AEs by intensity
Time Frame	within 29 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1	Group 1, Period 2	Group 1, Period 3	Group 2
▼ Arm/Group Description:	after 1st dose of MVA-BN	after 2nd dose of MVA-BN	after ACAM2000	ACAM2000
Overall Number of Participants Analyzed	220	208	196	213
Measure Type: Number Unit of Measure: Events				
Mild	233	141	143	163
Moderate	20	16	18	25
Severe	4	1	5	7

15. Secondary Outcome

Title	Solicited General AEs
▼ Description	Occurrence, intensity and relationship of solicited general AEs (body temperature [fever], headache, myalgia [muscle pain], chills, nausea, fatigue, malaise)
Time Frame	within 15 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
▼ Arm/Group Description:	after 1st dose of MVA-BN		after 2nd dose of MVA-BN		after ACAM2000		ACAM2000	
Overall Number of Participants Analyzed	208		193		187		200	
Measure Type: Count of Participants Unit of Measure: Participants								
Pyrexia, Grade 1, Related	0	0.0%	0	0.0%	0	0.0%	1	0.5%
Pyrexia, Grade 2, Related	2	1.0%	0	0.0%	1	0.5%	1	0.5%
Pyrexia, Grade 3, Related	0	0.0%	1	0.5%	0	0.0%	1	0.5%
Headache, Grade 1, Related	25	12.0%	11	5.7%	17	9.1%	38	19.0%
Headache, Grade 2, Related	6	2.9%	3	1.6%	7	3.7%	21	10.5%
Headache, Grade 3, Related	1	0.5%	2	1.0%	1	0.5%	9	4.5%
Myalgia, Grade 1, Related	28	13.5%	13	6.7%	15	8.0%	44	22.0%
Myalgia, Grade 2, Related	5	2.4%	5	2.6%	2	1.1%	21	10.5%
Myalgia, Grade 3, Related	0	0.0%	1	0.5%	0	0.0%	7	3.5%
Chills, Grade 1, Related	1	0.5%	0	0.0%	8	4.3%	19	9.5%
Chills, Grade 2, Related	0	0.0%	2	1.0%	2	1.1%	12	6.0%
Chills, Grade 3, Related	1	0.5%	0	0.0%	0	0.0%	2	1.0%
Nausea, Grade 1, Related	7	3.4%	4	2.1%	6	3.2%	21	10.5%
Nausea, Grade 2, Related	0	0.0%	2	1.0%	4	2.1%	12	6.0%
Nausea, Grade 3, Related	1	0.5%	0	0.0%	1	0.5%	6	3.0%
Fatigue, Grade 1, Related	29	13.9%	14	7.3%	21	11.2%	45	22.5%
Fatigue, Grade 2, Related	7	3.4%	2	1.0%	7	3.7%	30	15.0%
Fatigue, Grade 3, Related	1	0.5%	1	0.5%	1	0.5%	8	4.0%
Malaise, Grade 1, Related	16	7.7%	6	3.1%	12	6.4%	30	15.0%
Malaise, Grade 2, Related	5	2.4%	2	1.0%	8	4.3%	25	12.5%
Malaise, Grade 3, Related	2	1.0%	1	0.5%	2	1.1%	10	5.0%

16. Secondary Outcome

Title	Incidence of Lymphadenopathy
▼ Description	Incidence of events of Lymphadenopathy. Pooled solicited and unsolicited events.
Time Frame	within 29 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
▼ Arm/Group Description:	after 1st dose of MVA-BN		after 2nd dose of MVA-BN		after ACAM2000		ACAM2000	
Overall Number of Participants Analyzed	220		208		196		213	
Measure Type: Count of Participants Unit of Measure: Participants								
	24	10.9%	15	7.2%	17	8.7%	109	51.2%

17. Secondary Outcome

Title	Solicited Local AEs: Intensity
▼ Description	Incidence of solicited local AEs (pain, redness [erythema], swelling, induration, itching [pruritus])
Time Frame	within 15 days after vaccination

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
▼ Arm/Group Description:	after 1st dose of MVA-BN		after 2nd dose of MVA-BN		after ACAM2000		ACAM2000	
Overall Number of Participants Analyzed	208		193		187		200	
Measure Type: Count of Participants Unit of Measure: Participants								
Injection Site Pain, Grade 1	72	34.6%	49	25.4%	21	11.2%	58	29.0%
Injection Site Pain, Grade 2	21	10.1%	22	11.4%	6	3.2%	44	22.0%
Injection Site Pain, Grade 3	4	1.9%	0	0.0%	1	0.5%	33	16.5%
Injection Site Erythema, Grade 1	44	21.2%	40	20.7%	106	56.7%	105	52.5%
Injection Site Erythema, Grade 2	9	4.3%	10	5.2%	9	4.8%	81	40.5%
Injection Site Erythema, Grade 3	0	0.0%	0	0.0%	0	0.0%	5	2.5%
Injection Site Swelling, Grade 1	14	6.7%	16	8.3%	46	24.6%	120	60.0%
Injection Site Swelling, Grade 2	5	2.4%	6	3.1%	0	0.0%	17	8.5%
Injection Site Swelling, Grade 3	0	0.0%	0	0.0%	0	0.0%	1	0.5%
Injection Site Induration, Grade 1	23	11.1%	11	5.7%	44	23.5%	125	62.5%
Injection Site Induration, Grade 2	1	0.5%	2	1.0%	1	0.5%	7	3.5%
Injection Site Induration, Grade 3	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Injection Site Pruritus, Grade 1	24	11.5%	19	9.8%	99	52.9%	101	50.5%
Injection Site Pruritus, Grade 2	3	1.4%	1	0.5%	11	5.9%	60	30.0%
Injection Site Pruritus, Grade 3	2	1.0%	0	0.0%	1	0.5%	18	9.0%

18. Secondary Outcome

Title	Major Lesion Size, Major Erythema, and Major Induration Diameter
▼ Description	Daily measurement of major lesion size, major erythema, and major induration diameter (mm) based on physical appearance of vaccination site as documented in the memory aid. If the shape of the lesion, erythema [excludes lymphangitis], and induration observed was not round but rather asymmetrical, then the largest [or major] cross-sectional measurement was recorded.
Time Frame	Within 15 days after scarification with ACAM2000

▼ Outcome Measure Data

▼ Analysis Population Description
Full Analysis Set

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	220	213
Median (95% Confidence Interval) Unit of Measure: mm		
Maximum Lesion Diameter	5.0 (4.0 to 5.0)	11.5 (11.0 to 12.0)
Maximum Erythema	6.0 (5.0 to 7.0)	26.0 (25.0 to 30.0)
Maximum Induration	5.0 (4.0 to 9.0)	15.0 (13.0 to 16.0)

19. Secondary Outcome

Title	GMTs at the Peak Visits and Individual Peak Measured by Vaccinia-specific ELISA
▼ Description	Peak Visit was defined as Day 42 for Group 1 and Day 28 for Group 2. Individual Peak was the maximum titer per subject from Visit 1 to Visit 7 (Week 8) in Group 1 and maximum titer from Visit 1 to Visit 6 (Week 8) in Group 2. Titers below the detection limit are included with a value of 1.
Time Frame	within 8 weeks (for both groups)

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN [®] ; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000 [®] vaccine 4 weeks after the second MVA-BN [®] vaccination (Day 56). MVA-BN [®] : 0.5 ml MVA-BN [®] with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000 [®] will be administered at Day 0. ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Geometric Mean (95% Confidence Interval) Unit of Measure: Titer		
Peak Visit	1076.9 (956.8 to 1212.0)	194.6 (162.6 to 232.9)
Individual Peak	1105.2 (983.4 to 1242.0)	214.0 (177.8 to 257.6)

20. Secondary Outcome

Title	GMTs at the Individual Peak Measured by Vaccinia-specific PRNT
▼ Description	Individual Peak was the maximum titer per subject from Visit 1 to Visit 7 (Week 8) in Group 1 and maximum titer from Visit 1 to Visit 6 (Week 8) in Group 2. Titers below the detection limit are included with a value of 1.
Time Frame	within 8 weeks (for both groups)

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Geometric Mean (95% Confidence Interval) Unit of Measure: Titer		
	201.5 (178.5 to 227.5)	117.8 (102.3 to 135.7)

21. Secondary Outcome

Title	GMTs as Measured by Vaccinia-specific ELISA
▼ Description	GMT based on vaccinia-specific ELISA. Titers below the detection limit are included with a value of '1'.
Time Frame	within 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN [®] ; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000 [®] vaccine 4 weeks after the second MVA-BN [®] vaccination (Day 56). MVA-BN [®] : 0.5 ml MVA-BN [®] with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000 [®] will be administered at Day 0. ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Geometric Mean (95% Confidence Interval) Unit of Measure: Titer		
Week 0	1.2 (1.1 to 1.3)	1.2 (1.0 to 1.3)
Week 1	1.6 (1.3 to 2.0)	1.2 (1.0 to 1.3)
Week 2	104.9 (84.0 to 131.0)	21.9 (15.9 to 30.2)
Week 4	129.8 (107.1 to 157.2)	194.6 (162.6 to 232.9)
Week 6	1076.9 (956.8 to 1212.0)	149.2 (123.6 to 180.1)
Week 8	671.9 (597.2 to 755.8)	113.7 (93.2 to 138.7)
Week 12	550.5 (482.2 to 628.4)	NA ^[1] (NA to NA)

^[1] No week 12 visit for Group 2

22. Secondary Outcome

Title	GMTs as Measured by Vaccinia-specific PRNT
▼ Description	GMT based on vaccinia-specific PRNT. Titers below the detection limit are included with a value of '1'.
Time Frame	within 12 weeks

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Geometric Mean (95% Confidence Interval) Unit of Measure: Titer		
Week 0	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)
Week 1	1.1 (1.0 to 1.3)	1.0 (1.0 to 1.0)
Week 2	16.2 (13.0 to 20.1)	16.2 (13.1 to 20.0)
Week 4	16.9 (13.7 to 20.8)	79.3 (67.1 to 93.8)
Week 6	153.5 (134.3 to 175.6)	64.7 (54.9 to 76.2)
Week 8	118.2 (102.9 to 135.8)	67.1 (56.9 to 79.0)
Week 12	96.5 (80.1 to 116.2)	NA ^[1] (NA to NA)

^[1] No week 12 visit for Group 2

23. Secondary Outcome

Title	PRNT Seroconversion Rates at Peak Visits
▼ Description	Seroconversion rate based on PRNT. Seroconversion is defined as the appearance of antibody titers "greater than or equal" detection limit (2) for initially seronegative subjects, or a doubling or more of the antibody titer compared to Baseline titer for initially seropositive subjects. Percentages based on number of subjects with data available.
Time Frame	Group 1 at Week 6; Group 2 at Week 4

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN [®] ; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000 [®] vaccine 4 weeks after the second MVA-BN [®] vaccination (Day 56). MVA-BN [®] : 0.5 ml MVA-BN [®] with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000 [®] will be administered at Day 0. ACAM2000 [®] : 0.0025 ml ACAM2000 [®] , consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Measure Type: Number Number (95% Confidence Interval) Unit of Measure: percentage of subjects		
	100.0 (98.0 to 100.0)	97.3 (93.8 to 99.1)

24. Secondary Outcome

Title	ELISA Seroconversion Rates at Peak Visits
▼ Description	Seroconversion rate based on ELISA. Seroconversion is defined as the appearance of antibody titers "greater than or equal" detection limit (50) for initially seronegative subjects, or a doubling or more of the antibody titer compared to Baseline titer for initially seropositive subjects. Percentages based on number of subjects with data available.
Time Frame	Group 1 at Week 6; Group 2 at Week 4

▼ Outcome Measure Data

▼ Analysis Population Description
Per-protocol Set for Immunogenicity

Arm/Group Title	Group 1	Group 2
▼ Arm/Group Description:	Two vaccinations; MVA-BN®; administered 4 weeks apart (Day 0 and Day 28) followed by a single vaccination of ACAM2000® vaccine 4 weeks after the second MVA-BN® vaccination (Day 56). MVA-BN®: 0.5 ml MVA-BN® with a nominal titer of 1x10E8 TCID50, administered as a subcutaneous injection ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.	A single vaccination of ACAM2000® will be administered at Day 0. ACAM2000®: 0.0025 ml ACAM2000®, consisting of 2.5-12.5x10E5 plaque forming units of live vaccinia virus (VACV). Picked up with a bifurcated needle and administered by the percutaneous route (scarification) using 15 jabs of that bifurcated needle.
Overall Number of Participants Analyzed	185	186
Measure Type: Number Number (95% Confidence Interval) Unit of Measure: percentage of subjects		
	100 (98.0 to 100.0)	96.8 (93.1 to 98.8)

Adverse Events

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Time Frame	38 weeks for Group 1 and 30 weeks for Group 2			
Adverse Event Reporting Description	[Not Specified]			
Arm/Group Title	Group 1, Period 1	Group 1, Period 2	Group 1, Period 3	Group 2
▼ Arm/Group Description	after 1st dose of MVA-BN	after 2nd dose of MVA-BN	after ACAM2000	ACAM2000

All-Cause Mortality ⓘ								
	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
	Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)	
Total	0/220 (0.00%)		0/208 (0.00%)		0/196 (0.00%)		0/213 (0.00%)	
▼ Serious Adverse Events ⓘ								
	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	2/220 (0.91%)		0/208 (0.00%)		3/196 (1.53%)		3/213 (1.41%)	
Gastrointestinal disorders								
Haemorrhoids ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	0/196 (0.00%)	0	1/213 (0.47%)	1
Infections and infestations								
Appendicitis ^{†1}	1/220 (0.45%)	1	0/208 (0.00%)	0	0/196 (0.00%)	0	0/213 (0.00%)	0
Peritonsillar Abscess ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	1/196 (0.51%)	1	0/213 (0.00%)	0
Injury, poisoning and procedural complications								
Alcohol Poisoning ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	1/196 (0.51%)	1	0/213 (0.00%)	0
Road Traffic Accident ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	0/196 (0.00%)	0	1/213 (0.47%)	1
Tibia Fracture ^{†1}	1/220 (0.45%)	1	0/208 (0.00%)	0	0/196 (0.00%)	0	0/213 (0.00%)	0
Musculoskeletal and connective tissue disorders								
Rhabdomyolysis ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	0/196 (0.00%)	0	1/213 (0.47%)	1
Psychiatric disorders								
Suicidal Ideation ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	1/196 (0.51%)	1	0/213 (0.00%)	0
1 Term from vocabulary, MedDRA 20.0 † Indicates events were collected by systematic assessment								
▼ Other (Not Including Serious) Adverse Events ⓘ								
Frequency Threshold for Reporting Other Adverse Events	2%							
	Group 1, Period 1		Group 1, Period 2		Group 1, Period 3		Group 2	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	95/220 (43.18%)		63/208 (30.29%)		79/196 (40.31%)		88/213 (41.31%)	
Blood and lymphatic system disorders								
Lymphadenopathy ^{†1}	10/220 (4.55%)	11	6/208 (2.88%)	6	3/196 (1.53%)	3	23/213 (10.80%)	27
General disorders								
Axillary Pain ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	0/196 (0.00%)	0	5/213 (2.35%)	5

Injection Site Erythema ^{†1}	30/220 (13.64%)	30	23/208 (11.06%)	23	1/196 (0.51%)	1	0/213 (0.00%)	0
Injection Site Nodule ^{†1}	32/220 (14.55%)	38	13/208 (6.25%)	13	1/196 (0.51%)	1	0/213 (0.00%)	0
Vaccination Site Erythema ^{†1}	10/220 (4.55%)	10	7/208 (3.37%)	7	2/196 (1.02%)	2	0/213 (0.00%)	0
Vaccination Site Nodule ^{†1}	11/220 (5.00%)	11	3/208 (1.44%)	3	0/196 (0.00%)	0	2/213 (0.94%)	2
Vaccination Site Warmth ^{†1}	13/220 (5.91%)	13	10/208 (4.81%)	10	1/196 (0.51%)	1	0/213 (0.00%)	0
Infections and infestations								
Nasopharyngitis ^{†1}	7/220 (3.18%)	7	4/208 (1.92%)	4	6/196 (3.06%)	6	5/213 (2.35%)	5
Upper Respiratory Tract Infection ^{†1}	14/220 (6.36%)	14	14/208 (6.73%)	14	14/196 (7.14%)	14	14/213 (6.57%)	14
Injury, poisoning and procedural complications								
Laceration ^{†1}	5/220 (2.27%)	5	1/208 (0.48%)	1	4/196 (2.04%)	4	1/213 (0.47%)	1
Musculoskeletal and connective tissue disorders								
Arthralgia ^{†1}	4/220 (1.82%)	5	4/208 (1.92%)	4	2/196 (1.02%)	2	6/213 (2.82%)	6
Back Pain ^{†1}	7/220 (3.18%)	7	0/208 (0.00%)	0	4/196 (2.04%)	4	1/213 (0.47%)	1
Nervous system disorders								
Headache ^{†1}	4/220 (1.82%)	4	2/208 (0.96%)	2	6/196 (3.06%)	6	5/213 (2.35%)	5
Respiratory, thoracic and mediastinal disorders								
Cough ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	4/196 (2.04%)	4	1/213 (0.47%)	1
Skin and subcutaneous tissue disorders								
Dermatitis Contact ^{†1}	0/220 (0.00%)	0	0/208 (0.00%)	0	44/196 (22.45%)	44	49/213 (23.00%)	49
1 Term from vocabulary, MedDRA 20.0 † Indicates events were collected by systematic assessment								

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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