Clinical trial results:
The Long-Term Antibody Persistence Of MenACWY-TT Vaccine (PF-06866681) Versus Mencevax® ACWY In Healthy Adolescents And Adults And Booster Response To MenACWY-TT Vaccine Administered At 10 Years Postprimary Vaccination.

Summary

EudraCT number	2012-005639-10
Trial protocol	Outside EU/EEA
Global end of trial date	10 August 2018

Results information

Result version number	v1 (current)
This version publication date	01 August 2019
First version publication date	01 August 2019

Trial information

Trial identification

Sponsor protocol code	MENACWY-TT-099

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01934140
WHO universal trial number (UTN)	-
Other trial identifiers	Alias Study Number: C0921002

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.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	10 August 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 August 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Long-term persistence phase: Six, seven, eight, nine and ten years after primary vaccination with MenACWY-TT or Mencevax ACWY, in Study 107386 [NCT00356369]. To evaluate the long-term persistence of the serum bactericidal (antibody) titers induced by MenACWY-TT vaccine as compared to Mencevax ACWY when administered to individuals 11-55 years of age in terms of the percentage of subjects with Neisseria meningitidis serogroup A (MenA), serogroup C (MenC), serogroup W-135 (MenW-135), and serogroup Y (MenY) titers, greater than or equal to (>=)1:8, >=1:128 and geometric mean titres (GMTs) as measured by a serum bactericidal assay using rabbit complement (rSBA).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 April 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 311
Worldwide total number of subjects	311
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	0
Adults (18-64 years)	311
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Enrollment for this study (MENACWY-TT-99) started at Year 6 post primary vaccination in study 107386 [NCT00356369]. However, as approval was not obtained from authorities until after end of Year 6, hence no planned activities was done for Year 6.

Pre-assignment

Screening details:

In this study, subjects from the study 107386 [NCT00356369] were followed up for assessment of persistence of immune response. And those who consented received booster vaccination and were followed up for another 6 months.

Period 1

Period 1 title	Persistence Phase (Year 6-10)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	ACWY-TT group

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369].

Arm title	MenPS group

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenPS Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369].

Number of subjects in period 1	ACWY-TT group	MenPS group
Started	235	76
Completed	152	51
Not completed	83	25
Eligibility criteria not fulfilled	2	-
Migrated/moved from study area	31	10
Unspecified	24	6
Lost to follow-up	5	2
Missed at least 1 persistence visit	21	7

Period 2

Period 2 title	Booster Phase (6 Months)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	ACWY-TT group

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369].

Arm title	MenPS group

Arm description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Arm type	Experimental
Investigational medicinal product name	MenPS Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369].

Number of subjects in period 2	ACWY-TT group	MenPS group
Started	164	56
Vaccinated	164	56
Completed	159	53
Not completed	5	3
Missed at least 1 booster visit	2	1
Migrated/moved from study area	2	2
Lost to follow-up	1	-

Baseline characteristics

Reporting groups	
Reporting group title	ACWY-TT group
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.	
Reporting group title	MenPS group
Reporting group description:	
Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.	

Reporting group values	ACWY-TT group	MenPS group	Total
Number of subjects	235	76	311
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	235	76	311
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	25.3	25.2	
standard deviation	± 8.2	± 8.4	-
Sex: Female, Male Units: Subjects			
Female	108	40	148
Male	127	36	163
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	235	76	311
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0

White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	235	76	311
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	ACWY-TT group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 milliliter (mL) dose of meningococcal serogroups A, C, W 135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Reporting group title	MenPS group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Reporting group title	ACWY-TT group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Reporting group title	MenPS group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Primary: Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titres Greater Than or Equal to (>=) 1:8 and >=1:128 For Each of the 4 Serogroups After 6 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titres Greater Than or Equal to (>=) 1:8 and >=1:128 For Each of the 4 Serogroups After 6 Years of Primary Vaccination[1]

End point description:

Serogroups included Neisseria meningitidis serogroup A (MenA), Neisseria meningitidis serogroup C (MenC), Neisseria meningitidis serogroup W-135 (MenW-135) and Neisseria meningitidis serogroup Y (MenY). Data was not collected and analyzed for this endpoint because approval was not obtained from the authorities for Year 6 activities.

End point type	Primary

End point timeframe:

After 6 years of primary vaccination

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[2]	0[3]		
Units: percentage of subjects				
number (confidence interval 95%)	(to)	(to)		

Notes:

[2] - Data was not collected and analysed, Hence no activity was done for Year 6.

[3] - Data was not collected and analysed, Hence no activity was done for Year 6.

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 7 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 7 Years of Primary Vaccination[4]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "Overall Number of Subjects Analysed" (N) signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

After 7 years of primary vaccination

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	206	65		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	88.3 (83.2 to 92.4)	67.7 (54.9 to 78.8)		
rSBA-MenC: >=1:8	82.5 (76.6 to 87.4)	76.9 (64.8 to 86.5)		
rSBA-MenW-135: >=1:8	60.7 (53.7 to 67.4)	23.1 (13.5 to 35.2)		
rSBA-MenY: >=1:8	80.1 (74.0 to 85.3)	46.2 (33.7 to 59.0)		
rSBA-MenA: >=128	73.8 (67.2 to 79.7)	46.2 (33.7 to 59.0)		
rSBA-MenC: >=1:128	61.7 (54.6 to 68.3)	61.5 (48.6 to 73.3)		
rSBA-MenW-135: >=1:128	52.4 (45.4 to 59.4)	16.9 (8.8 to 28.3)		

rSBA-MenY: >=1:128	76.7 (70.3 to 82.3)	38.5 (26.7 to 51.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 8 Years of Primary Vaccination

End point title	Persistence Phase: Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 8 Years of Primary Vaccination[5]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here,"Number analyzed"(n): subjects analyzed for specified serogroup and "N" signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

After 8 years of primary vaccination

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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	208	67		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8 (n=208, 67)	76.0 (69.6 to 81.6)	56.7 (44.0 to 68.8)		
rSBA-MenC: >=1:8 (n=204, 67)	86.3 (80.8 to 90.7)	80.6 (69.1 to 89.2)		
rSBA-MenW-135: >=1:8 (n=207, 67)	66.2 (59.3 to 72.6)	23.9 (14.3 to 35.9)		
rSBA-MenY: >=1:8 (n=206, 67)	76.2 (69.8 to 81.9)	40.3 (28.5 to 53.0)		
rSBA-MenA: >=1:128 (n=208, 67)	60.6 (53.6 to 67.3)	40.3 (28.5 to 53.0)		
rSBA-MenC: >=1:28 (n=204, 67)	68.1 (61.3 to 74.5)	64.2 (51.5 to 75.5)		
rSBA-MenW-135: >=1:128 (n=207, 67)	60.9 (53.9 to 67.6)	16.4 (8.5 to 27.5)		
rSBA-MenY: >=1:128 (n=206, 67)	70.9 (64.2 to 77.0)	37.3 (25.8 to 50.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase:Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 9 Years of Primary Vaccination

End point title	Persistence Phase:Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 9 Years of Primary Vaccination[6]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

After 9 years of primary vaccination

Notes:

[6] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	190	61		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	82.6 (76.5 to 87.7)	65.6 (52.3 to 77.3)		
rSBA-MenC: >=1:8	89.5 (84.2 to 93.5)	90.2 (79.8 to 96.3)		
rSBA-MenW-135: >=1:8	55.8 (48.4 to 63.0)	9.8 (3.7 to 20.2)		
rSBA-MenY: >=1:8	89.5 (84.2 to 93.5)	57.4 (44.1 to 70.0)		
rSBA-MenA: >=1:128	75.3 (68.5 to 81.2)	59.0 (45.7 to 71.4)		
rSBA-MenC: >=1:128	66.8 (59.7 to 73.5)	67.2 (54.0 to 78.7)		
rSBA-MenW-135: >=1:128	50.5 (43.2 to 57.8)	9.8 (3.7 to 20.2)		
rSBA-MenY: >=1:128	86.3 (80.6 to 90.9)	50.8 (37.7 to 63.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase:Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 10 Years of Primary Vaccination

End point title	Persistence Phase:Percentage of Subjects With rSBA Titres >= 1:8 and >=1:128 For Each of the 4 Serogroups After 10 Years of Primary Vaccination[7]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available

assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure and "n": subjects analyzed for specified serogroup.

End point type	Primary

End point timeframe:

After 10 years of primary vaccination

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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	54		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8 (n=162, 54)	76.5 (69.3 to 82.8)	70.4 (56.4 to 82.0)		
rSBA-MenC: >=1:8 (n=161, 54)	90.7 (85.1 to 94.7)	88.9 (77.4 to 95.8)		
rSBA-MenW-135: >=1:8 (n=161, 54)	70.2 (62.5 to 77.1)	24.1 (13.5 to 37.6)		
rSBA-MenY: >=1:8 (n=161, 54)	87.0 (80.8 to 91.7)	64.8 (50.6 to 77.3)		
rSBA-MenA: >=1:128 (n=162, 54)	67.9 (60.1 to 75.0)	57.4 (43.2 to 70.8)		
rSBA-MenC: >=1:128 (n=161, 54)	72.7 (65.1 to 79.4)	68.5 (54.4 to 80.5)		
rSBA-MenW-135: >=1:128 (n=161, 54)	64.6 (56.7 to 72.0)	22.2 (12.0 to 35.6)		
rSBA-MenY: >=1:128 (n=161, 54)	83.2 (76.5 to 88.6)	53.7 (39.6 to 67.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase:Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 6 Years of Primary Vaccination

End point title	Persistence Phase:Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 6 Years of Primary Vaccination[8]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50 percentage (%) reduction of meningococcal colony-forming units. Data was not collected and analyzed for this endpoint because approval was not obtained from the authorities for Year 6 activities.

End point type	Primary

End point timeframe:

After 6 years of primary vaccination

Notes:

[8] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[9]	0[10]		
Units: titres				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[9] - Data was not collected and analysed, Hence no activity was done for Year 6.

[10] - Data was not collected and analysed, Hence no activity was done for Year 6.

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 7 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 7 Years of Primary Vaccination[11]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50% reduction of meningococcal colony-forming units. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

After 7 years of primary vaccination

Notes:

[11] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	206	65		
Units: titres				
geometric mean (confidence interval 95%)				
rSBA-MenA	220.8 (167.2 to 291.5)	54.5 (31.1 to 95.8)		
rSBA-MenC	105.3 (79.7 to 139.1)	156.7 (82.7 to 297.1)		
rSBA-MenW-135	83.2 (57.0 to 121.5)	10.0 (6.3 to 15.9)		
rSBA-MenY	270.2 (195.2 to 373.8)	32.7 (17.8 to 60.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4

Serogroups After 8 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 8 Years of Primary Vaccination[12]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50% reduction of meningococcal colony-forming units. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure and "n"= subjects analyzed for specified serogroup.

End point type	Primary

End point timeframe:

After 8 years of primary vaccination

Notes:

[12] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	208	67		
Units: titres				
geometric mean (confidence interval 95%)				
rSBA-MenA (n=208, 67)	104.8 (77.1 to 142.4)	44.1 (24.3 to 80.0)		
rSBA-MenC (n=204, 67)	155.4 (118.3 to 204.0)	240.6 (125.4 to 461.8)		
rSBA-MenW-135 (n=207, 67)	119.7 (82.8 to 173.1)	10.8 (6.7 to 17.5)		
rSBA-MenY (n=206, 67)	181.6 (130.2 to 253.3)	26.0 (14.5 to 46.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 9 Years of Primary Vaccination

End point title	Persistence Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 9 Years of Primary Vaccination[13]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50% reduction of meningococcal colony-forming units. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure.

End point type	Primary

End point timeframe:

After 9 years of primary vaccination

Notes:

[13] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	190	61		
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	227.8 (165.0 to 314.5)	81.2 (44.2 to 149.4)		
rSBA-MenC	173.3 (129.9 to 231.1)	264.9 (147.7 to 474.9)		
rSBA-MenW-135	71.7 (48.0 to 107.0)	6.7 (4.5 to 10.0)		
rSBA-MenY	460.6 (346.2 to 612.7)	57.8 (30.6 to 109.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Persistence Phase:Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 10 Years of Primary Vaccination

End point title	Persistence Phase:Geometric Mean Titres With rSBA for Each of the 4 Serogroups After 10 Years of Primary Vaccination[14]

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50% reduction of meningococcal colony-forming units. All eligible subjects who received primary vaccination with MenACWY-TT or Mencevax ACWY during study 107386 [NCT00356369], had available assay results for at least 1 tested antigen. Here, "N" signifies number of subjects evaluable for this measure and " n": subjects analyzed for specified serogroup.

End point type	Primary

End point timeframe:

After 10 years of primary vaccination

Notes:

[14] - 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: Only descriptive data was planned to be analysed for this endpoint.

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	162	54		
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (n=162, 54)	142.5 (100.4 to 202.1)	73.7 (40.9 to 132.8)		
rSBA-MenC (n=161, 54)	181.4 (134.6 to 244.4)	234.0 (122.3 to 447.9)		
rSBA-MenW-135 (n=161, 54)	161.5 (104.8 to 248.9)	11.9 (6.8 to 21.0)		
rSBA-MenY (n=161, 54)	387.0 (274.1 to 546.4)	63.2 (33.4 to 119.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With rSBA Titres >=1:8 and >=1:128 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With rSBA Titres >=1:8 and >=1:128 For Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. All eligible subjects who received primary vaccination in study107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099; for whom assay results are available for antibodies against at least 1 study vaccine antigen component for blood sample taken 1 month after vaccination. N=number of subjects evaluable for this measure.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	52		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA: >=1:8	100.0 (97.6 to 100.0)	100.0 (93.2 to 100.0)		
rSBA-MenC: >=1:8	100.0 (97.6 to 100.0)	98.1 (89.7 to 100.0)		
rSBA-MenW-135: >=1:8	100.0 (97.6 to 100.0)	98.1 (89.7 to 100.0)		
rSBA-MenY: >=1:8	100.0 (97.6 to 100.0)	100.0 (93.2 to 100.0)		
rSBA-MenA: >=1:128	100.0 (97.6 to 100.0)	100.0 (93.2 to 100.0)		
rSBA-MenC: >=1:128	100.0 (97.6 to 100.0)	96.2 (86.8 to 99.5)		
rSBA-MenW-135: >=1:128	100.0 (97.6 to 100.0)	98.1 (89.7 to 100.0)		
rSBA-MenY: >=1:128	100.0 (97.6 to 100.0)	100.0 (93.2 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point title	Booster Phase: Geometric Mean Titres With rSBA for Each of the 4 Serogroups at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA titres expressed as the reciprocal of the highest serum last dilution resulting in at least 50% reduction of meningococcal colony-forming units. All eligible subjects who received primary vaccination in study107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099; for whom assay results are available for antibodies against at least 1 study vaccine antigen component for blood sample taken 1 month after vaccination. N=number of subjects evaluable for this measure.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	52		
Units: titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	4059.5 (3383.8 to 4870.2)	3584.8 (2750.7 to 4672.0)		
rSBA-MenC	13823.5 (10839.7 to 17628.7)	3444.3 (1998.5 to 5936.0)		
rSBA-MenW-135	23431.0 (17351.4 to 31640.7)	5792.6 (3585.9 to 9357.4)		
rSBA-MenY	8958.4 (7601.6 to 10557.5)	5137.8 (3528.2 to 7481.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With rSBA Booster Response at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With rSBA Booster Response at 1 Month After Booster Vaccination

End point description:

Serogroups included MenA, MenC, MenW-135 and MenY. rSBA booster vaccine responses for serogroups A, C, W-135 and Y defined as: for initially seronegative subjects (pre-vaccination titer below the cut-off of 1:8) had rSBA antibody titers >= 1:32, 1 month after vaccination, and for initially seropositive subjects (pre-vaccination titer >= 1:8) had rSBA antibody titers at least 4 times the pre-vaccination antibody titers, 1 month after vaccination. Data reported below is including both seropositive and seronegative subjects. All eligible subjects: received primary vaccination in study 107386[NCT00356369] and booster dose in study MENACWY-099;assay results available for antibodies against at least 1 study vaccine antigen component in blood sample taken 1 month post vaccination. N= subjects evaluable for measure, n= subjects analyzed for specified serogroups.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	52		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA (n= 155, 52)	87.7 (81.5 to 92.5)	88.5 (76.6 to 95.6)		
rSBA-MenC (n= 154, 52)	90.9 (85.2 to 94.9)	75.0 (61.1 to 86.0)		
rSBA-MenW-135 (n= 154, 52)	94.2 (89.2 to 97.3)	96.2 (86.8 to 99.5)		
rSBA-MenY (n= 154, 52)	83.8 (77.0 to 89.2)	92.3 (81.5 to 97.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Antibodies Against–Tetanus Toxoid (Anti-TT) Concentrations >=0.1 International Units Per Millilitre (IU/mL), >=1.0 IU/mL at 1 Month After Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Antibodies Against–Tetanus Toxoid (Anti-TT) Concentrations >=0.1 International Units Per Millilitre (IU/mL), >=1.0 IU/mL at 1 Month After Booster Vaccination

End point description:

Tetanus toxoid (TT) was used as carrier in tetravalent meningococcal ACWY conjugate vaccine. Percentage of subjects with anti-TT concentration >=0.1 IU/mL, >=1.0 IU/mL were summarized. All eligible subjects who received primary vaccination in study107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099; for whom assay results are available for antibodies against at least 1 study vaccine antigen component for blood sample taken 1 month after vaccination. N= subjects evaluable for this measure.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	52		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-TT >= 0.1 IU/mL	99.4 (96.5 to 100.0)	98.1 (89.7 to 100.0)		

Anti-TT >= 1.0 IU/mL	94.8 (90.1 to 97.7)	88.5 (76.6 to 95.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Geometric Mean Concentrations (GMCs) of Antibodies Against–Tetanus Toxoid (Anti-TT) at 1 Month After Booster Vaccination

End point title	Booster Phase: Geometric Mean Concentrations (GMCs) of Antibodies Against–Tetanus Toxoid (Anti-TT) at 1 Month After Booster Vaccination

End point description:

TT was used as carrier in tetravalent meningococcal ACWY conjugate vaccine. Percentage of subjects with anti-TT concentration >=0.1 IU/mL, >=1.0 IU/mL were summarized. All eligible subjects who received primary vaccination in study107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099; for whom assay results are available for antibodies against at least 1 study vaccine antigen component for blood sample taken 1 month after vaccination. N= subjects evaluable for this measure.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	155	52		
Units: IU/mL				
geometric mean (confidence interval 95%)	7.163 (5.958 to 8.613)	7.650 (4.888 to 11.973)		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Solicited Local and General Adverse Events up to 4 Days Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Solicited Local and General Adverse Events up to 4 Days Post Booster Vaccination

End point description:

Solicited local events:1)pain(Grade[G]:0=none,1=mild,neither interfered nor prevented normal activities,2=moderate, interfered normal activities,3=severe, prevented normal activities),2)redness, and 3)swelling (record greatest surface diameter in millimetre[mm] as 0 to <=20 mm, >20 to <=50 mm,>50 mm). Solicited general events: 1) fatigue,2) gastrointestinal(GI) events(nausea, vomiting, diarrhea and/or abdominal pain,3) headache(G: 0=normal,1=mild, easily tolerated,2=moderate, interfered with normal activity,3=severe, prevented normal activity),and 4)fever (G: Fever (G: 1= >=37.5 degree Celsius [°C] - <=38.0 degree C, 2= >38.0 degree C - <=39.0 degree C, 3= >39.0 degree C). 'Related'=relationship to study vaccine assessed by investigator. Medical advice=medical

advice received to resolve any event. All eligible subjects who received primary vaccination in study107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099. n: subjects analyzed for specified categories.

End point type	Secondary
End point timeframe:	
up to 4 days post booster vaccination	

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)				
All pain (n= 159, 53)	27.0	26.4		
Pain: Grade 1 (n= 159, 53)	20.8	24.5		
Pain: Grade 2 (n= 159, 53)	5.7	1.9		
Severe pain: Grade 3 (n= 159, 53)	0.6	0.0		
All redness (n= 159, 53)	5.7	3.8		
Redness: 0 to <=20 mm (n= 159, 53)	5.7	3.8		
Redness: >20 to <=50 mm (n= 159, 53)	0.0	0.0		
Redness: >50 mm (n= 159, 53)	0.0	0.0		
All swelling (n= 159, 53)	3.8	5.7		
Swelling: 0 to <=20 mm (n= 159, 53)	3.8	5.7		
Swelling: >20 to <=50 mm (n= 159, 53)	0.0	0.0		
Swelling: >50 mm (n= 159, 53)	0.0	0.0		
All fatigue (n= 159, 53)	14.5	15.1		
Fatigue: Grade 1 (n= 159, 53)	10.7	15.1		
Fatigue: Grade 2 (n= 159, 53)	3.1	0.0		
Fatigue: Grade 3 (n= 159, 53)	0.6	0.0		
Fatigue: Related fatigue (n= 159, 53)	12.6	15.1		
Fatigue: Grade 3 Related (n= 159, 53)	0.6	0.0		
All fever (n= 159, 53)	6.9	5.7		
Fever: Grade 1 (n= 159, 53)	6.3	5.7		
Fever: Grade 2 (n= 159, 53)	0.6	0.0		
Fever: Grade 3 (n= 159, 53)	0.0	0.0		
Fever: Related (n= 159, 53)	6.9	5.7		
Fever: Grade 3 related (n= 159, 53)	0.0	0.0		
All GI (n= 159, 53)	4.4	1.9		
GI: Grade 1 (n= 159, 53)	3.8	1.9		
GI: Grade 2 (n= 159, 53)	0.0	0.0		
GI: Grade 3 (n= 159, 53)	0.6	0.0		
GI: Related (n= 159, 53)	3.8	1.9		
GI: Grade 3 related (n= 159, 53)	0.6	0.0		
All headache (n= 159, 53)	15.7	9.4		
Headache: Grade 1 (n= 159, 53)	12.6	9.4		
Headache: Grade 2 (n= 159, 53)	1.9	0.0		
Headache: Grade 3 (n= 159, 53)	1.3	0.0		
Headache: Related (n= 159, 53)	13.8	9.4		

Headache: Grade 3 related (n= 159, 53)	1.3	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Unsolicited Adverse Events up to 31 Days Post Booster Vaccination

End point title	Booster Phase: Percentage of Subjects With Unsolicited Adverse Events up to 31 Days Post Booster Vaccination

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. All eligible subjects who received primary vaccination in study 107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099.

End point type	Secondary

End point timeframe:

up to 31 days post booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)	9.1	3.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Serious Adverse Events (SAEs) From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point title	Booster Phase: Percentage of Subjects With Serious Adverse Events (SAEs) From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. All eligible subjects who received primary vaccination in study 107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With New Onset Chronic Illness From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point title	Booster Phase: Percentage of Subjects With New Onset Chronic Illness From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point description:

New onset chronic illness included autoimmune disorders, asthma, type I diabetes, and allergies. All eligible subjects who received primary vaccination in study 107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Guillain-Barre Syndrome (GBS) From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point title	Booster Phase: Percentage of Subjects With Guillain-Barre Syndrome (GBS) From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point description:

Guillain-Barre syndrome (GBS) is a rare neurological disorder in which the body's immune system mistakenly attacks part of its peripheral nervous system—the network of nerves located outside of the brain and spinal cord. GBS can range from a very mild case with brief weakness to nearly devastating paralysis, leaving the person unable to breathe independently. All eligible subjects who received primary vaccination in study 107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Booster Phase: Percentage of Subjects With Meningococcal Disease From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point title	Booster Phase: Percentage of Subjects With Meningococcal Disease From Booster Vaccination up to End of Study (6 Months Post Booster Vaccination)

End point description:

Meningococcal disease describes infections caused by the bacterium Neisseria meningitidis (also termed meningococcus). It causes two life threatening diseases: meningococcal meningitis and fulminant meningococcemia which often occur together. Meningococcal meningitis is defined as an inflammatory response to bacterial infection of leptomeninges (pia-arachnoid) and the sub-arachnoid space. Meningococcal meningococcemia is meningococcal septicemia when the bacteria circulate and multiply in blood and involve multiple organs. It can cause multi-organ failure and severe disability or death. All eligible subjects who received primary vaccination in study 107386 [NCT00356369], received booster dose of vaccine in study MENACWY-099.

End point type	Secondary

End point timeframe:

Up to 6 months post booster vaccination

End point values	ACWY-TT group	MenPS group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	164	56		
Units: percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

For persistence phase: Through 4 years (7, 8, 9 and 10 years post primary vaccination) Non-SAEs not collected for persistence phase; Booster phase: upto 6 months after booster vaccination;Local and General events: upto 4 days post booster vaccination.

Adverse event reporting additional description:

Same event may appear as both AE and SAE. An event may be categorized as serious in 1 subject and non-serious in other, or subject may experienced both SAE and non-SAE. Persistence Phase: all subjects enrolled in MENACWY-099. Booster Phase: all eligible subject who received primary vaccination in 107386[NCT00356369], booster vaccine in MENACWY-099.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Booster Phase: ACWY-TT group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Reporting group title	Booster Phase: MenPS group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MencevaxACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Reporting group title	Persistence phase: ACWY-TT group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of MenACWY-TT vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99), they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination in 107386 [NCT00356369], and were followed up for 6 months after booster vaccination.

Reporting group title	Persistence phase: MenPS group

Reporting group description:

Persistence phase was followed up by booster phase. Persistence phase: Subjects received a single 0.5 mL dose of Mencevax ACWY vaccine intramuscularly, as primary vaccination in study 107386 [NCT00356369]. Then, in this study (MENACWY-TT-99) they were evaluated for long-term persistence of immune response for 4 years (7, 8, 9 and 10 years post primary vaccination). Booster phase: All eligible subjects from persistence phase who provided informed consent to enroll in booster phase, received a single 0.5 mL booster dose of MenACWY-TT vaccine intramuscularly in this study, 10 years post primary vaccination, and were followed up for 6 months after booster vaccination.

Serious adverse events	Booster Phase: ACWY-TT group	Booster Phase: MenPS group	Persistence phase: ACWY-TT group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 164 (0.00%)	0 / 56 (0.00%)	0 / 235 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Persistence phase: MenPS group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 76 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Booster Phase: ACWY-TT group	Booster Phase: MenPS group	Persistence phase: ACWY-TT group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 164 (40.24%)	20 / 56 (35.71%)	0 / 235 (0.00%)
Nervous system disorders			
Headache	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	25 / 164 (15.24%)	5 / 56 (8.93%)	0 / 235 (0.00%)
occurrences (all)	40	6	0
General disorders and administration site conditions			
Fatigue	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	23 / 164 (14.02%)	8 / 56 (14.29%)	0 / 235 (0.00%)
occurrences (all)	42	9	0
Influenza like illness	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	2 / 164 (1.22%)	0 / 56 (0.00%)	0 / 235 (0.00%)
occurrences (all)	2	0	0
Injection site erythema (redness)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			

subjects affected / exposed	9 / 164 (5.49%)	2 / 56 (3.57%)	0 / 235 (0.00%)
occurrences (all)	18	3	0
Injection site pain (pain at injection site)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	43 / 164 (26.22%)	14 / 56 (25.00%)	0 / 235 (0.00%)
occurrences (all)	73	19	0
Injection site swelling (swelling)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	6 / 164 (3.66%)	3 / 56 (5.36%)	0 / 235 (0.00%)
occurrences (all)	8	4	0
Gastrointestinal disorders			
Gastrointestinal	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	7 / 164 (4.27%)	1 / 56 (1.79%)	0 / 235 (0.00%)
occurrences (all)	12	1	0
Infections and infestations			
Nasopharyngitis	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	3 / 164 (1.83%)	0 / 56 (0.00%)	0 / 235 (0.00%)
occurrences (all)	3	0	0
Pharyngotonsillitis	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 164 (0.00%)	1 / 56 (1.79%)	0 / 235 (0.00%)
occurrences (all)	0	1	0
Post procedural infection	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 164 (0.00%)	1 / 56 (1.79%)	0 / 235 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	3 / 164 (1.83%)	0 / 56 (0.00%)	0 / 235 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Persistence phase: MenPS group		
Total subjects affected by non-serious adverse events			

subjects affected / exposed	0 / 76 (0.00%)		
Nervous system disorders			
Headache	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Influenza like illness	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Injection site erythema (redness)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Injection site pain (pain at injection site)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Injection site swelling (swelling)	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Gastrointestinal	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
alternative assessment type: Systematic			
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		

Infections and infestations			
Nasopharyngitis	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Pharyngotonsillitis	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Post procedural infection	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection	Additional description: Non-SAEs were not collected for persistence phase of the study, hence actual population exposed is "0". Current presentation is a resolution of database limitation.		
subjects affected / exposed	0 / 76 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Enrollment for this study (MENACWY-TT-99) started at Year 6. However, Study visit for Year 6 was not done because approval was not obtained from the authorities until after the end of the Year 6. Hence, no planned activities were done for Year 6.

Notes: