Clinical trial results:
A Phase 1, Randomized, Single Dose, Blinded, Dose-Escalation Study to Assess Safety, Tolerability and Immunogenicity of ASP3772, a Pneumococcal Vaccine, in Toddlers 12 to 15 Months of Age in Comparison to an Active Comparator

Summary

EudraCT number	2019-004503-12
Trial protocol	Outside EU/EEA
Global end of trial date	06 April 2022

Results information

Result version number	v1 (current)
This version publication date	26 October 2022
First version publication date	26 October 2022

Trial information

Trial identification

Sponsor protocol code	3772-CL-2001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04525599
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Affinivax
Sponsor organisation address	301 Binney Street, Suite 302, Cambridge, Massachusetts (MA), United States, 02142
Public contact	Affinivax, Affinivax, 1 617-465-0865, contact@affinivax.com
Scientific contact	Affinivax, Affinivax, 1 617-465-0865, contact@affinivax.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002641-PIP01-19
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 April 2022
Global end of trial reached?	Yes
Global end of trial date	06 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability of 3 dose levels of ASP3772, in comparison to the active comparator PCV13 in toddlers approximately 12 to 15 months of age who have previously been administered the routine 3-dose series of PCV13.

Protection of trial subjects:

The toddlers were observed for safety reactogenicity events, including daily body temperature measurements and both local and systemic tolerability assessments. Oversight of safety and dose escalation was provided by Dose Escalation Committee.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 September 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 75
Worldwide total number of subjects	75
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)	75
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

1 of 75 subjects was randomized to PCV13 group but administered ASP3772. Therefore, all the primary analysis and immunogenicity analysis were done on the Safety Analysis Set based on the treatment actually received, and the results are presented here.

Pre-assignment

Screening details:

Of 85 subjects with informed consent:7 were screen failures, 3 were withdrawn by their parent/guardian. 75 subjects were randomized and dosed. 1 subject randomized to PCV13 group received ASP3772 5µg dose instead of PCV13, thus contributed to ASP3772 5µg group.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1, ASP3772 Low Dose

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

Arm type	Experimental
Investigational medicinal product name	ASP3772
Investigational medicinal product code	
Other name	AFX3772
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Low dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

Arm title	Group 2, ASP3772 Medium Dose

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

Arm type	Experimental
Investigational medicinal product name	ASP3772
Investigational medicinal product code	
Other name	AFX3772
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Medium dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

Arm title	Group 3, ASP3772 High Dose

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.

Arm type	Experimental

Investigational medicinal product name	ASP3772
Investigational medicinal product code	
Other name	AFX3772
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

High dose of ASP3772 was administered into anterolateral right or left thigh muscle on Day 1.

Arm title	Comparator PCV13

Arm description:

Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.

Arm type	Active comparator
Investigational medicinal product name	PCV13
Investigational medicinal product code	
Other name	Prevnar 13
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

PCV13 was administered into anterolateral right or left thigh muscle on Day 1.

Number of subjects in period 1	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose
Started	15	15	16
Completed	15	14	16
Not completed	0	1	0
Lost to follow-up	-	1	-

Number of subjects in period 1	Comparator PCV13
Started	29
Completed	29
Not completed	0
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1, ASP3772 Low Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 2, ASP3772 Medium Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 3, ASP3772 High Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Comparator PCV13
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.	

Reporting group values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose
Number of subjects	15	15	16
Age Categorical			
The Age characteristics analysis was performed on the Safety Analysis Set (SAF).			
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)	15	15	16
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
The Age characteristics analysis was performed on the Safety Analysis Set (SAF).			
Units: months			
arithmetic mean	13.3	13.1	13.3
standard deviation	± 1.3	± 0.8	± 1.1
Gender Categorical			
The Gender categorical analysis was performed on the Safety Analysis Set (SAF).			
Units: Subjects			
Female	7	11	6
Male	8	4	10
Race/Ethnicity, Customized			
The Race/Ethnicity analysis was performed on the Safety Analysis Set (SAF).			
Units: Subjects			
White	10	12	10

Black or African American	5	1	3
American Indian or Alaska Native	0	0	1
Other	0	2	2

Reporting group values	Comparator PCV13	Total	
Number of subjects	29	75	
Age Categorical			
The Age characteristics analysis was performed on the Safety Analysis Set (SAF).			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	29	75	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
The Age characteristics analysis was performed on the Safety Analysis Set (SAF).			
Units: months			
arithmetic mean	13.1		
standard deviation	± 1.1	-	
Gender Categorical			
The Gender categorical analysis was performed on the Safety Analysis Set (SAF).			
Units: Subjects			
Female	13	37	
Male	16	38	
Race/Ethnicity, Customized			
The Race/Ethnicity analysis was performed on the Safety Analysis Set (SAF).			
Units: Subjects			
White	21	53	
Black or African American	5	14	
American Indian or Alaska Native	0	1	
Other	3	7	

End points

End points reporting groups

Reporting group title	Group 1, ASP3772 Low Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose (1 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 2, ASP3772 Medium Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of medium dose (2 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 3, ASP3772 High Dose
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of high dose (5 µg) of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Comparator PCV13
Reporting group description:	
Healthy toddlers aged approximately 12 to 15 months received a single IM injection of the approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.	

Primary: Number of Subjects with Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Subjects with Treatment Emergent Adverse Events (TEAEs)[1]
End point description:	
An AE is any untoward medical occurrence in a subject administered a study vaccine, and which does not necessarily have to have a causal relationship with this vaccination. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product whether or not considered related to the medicinal product. A TEAE is defined as any AE with onset within 30 days from study vaccine administration (Day 1-Day 30). Analysis was performed on the Safety Analysis Set (SAF) which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.	
End point type	Primary
End point timeframe:	
Day 1 to Day 30	
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: This is a descriptive endpoint with no statistical analyses.	

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Subjects				
Vaccine-Related TEAEs	1	1	0	2
Serious TEAEs	0	0	0	2
Always Serious TEAE	0	0	0	1
Medically Attended TEAE	5	6	9	14

Statistical analyses

No statistical analyses for this end point

Primary: Maximum Body Temperature over 7 days Post-vaccination

End point title	Maximum Body Temperature over 7 days Post-vaccination[2]

End point description:

Body temperature was assessed by Grades range from 1 to 4. Grade 1= mild (38.0 – 38.4 Degrees Celsius [°C]); Grade 2 = moderate (38.5 – 38.9°C); Grade 3 = severe (39.0 – 40°C); Grade 4 = potentially life-threatening (> 40).
Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Primary

End point timeframe:

7 Days Post-vaccination

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This is a descriptive endpoint with no statistical analyses.

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Subjects				
No Fever	14	15	15	25
38.0 – 38.4°C	1	0	0	2
38.5 – 38.9°C	0	0	1	1
39.0 – 40.0°C	0	0	0	1
> 40.0°C	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity Assessed by Number of Solicited Local Reactions

End point title	Reactogenicity Assessed by Number of Solicited Local

End point description:

Assessed solicited local reactions were tenderness, redness/erythema, induration, swelling and administration site movement restriction.
Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Primary

End point timeframe:

Day 1 to Day 7

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This is a descriptive endpoint with no statistical analyses.

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Subjects				
Tenderness	9	7	4	8
Erythema/Redness	4	7	2	8
Induration	4	5	3	10
Swelling	3	4	2	6
Administration Site Movement Restriction	0	2	2	2

Statistical analyses

No statistical analyses for this end point

Primary: Reactogenicity assessed by Number of Solicited Systemic Reactions

End point title	Reactogenicity assessed by Number of Solicited Systemic Reactions[4]

End point description:

Assessed solicited systemic reactions were irritability, diarrhea, decrease of appetite, increase or decrease in sleep, vomiting, and fever.
Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Primary

End point timeframe:

Day 1 to Day 7

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: This is a descriptive endpoint with no statistical analyses.

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Subjects				
Irritability	10	10	8	17
Diarrhea	4	7	7	5
Decrease of Appetite	5	5	4	9
Increase in Sleep	3	4	4	9
Decrease in Sleep	4	2	2	6
Vomiting	3	4	2	6
Fever	1	0	1	4

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with Serotype-specific Immunoglobulin G (IgG) Concentration of greater than or equal to (>=) 0.35 microgram per millilitre (µg/mL)

End point title	Percentage of Subjects with Serotype-specific Immunoglobulin G (IgG) Concentration of greater than or equal to (>=) 0.35 microgram per millilitre (µg/mL)

End point description:

Immunogenicity was measured in terms of percentage of subjects with serotype-specific IgG concentration >=0.35 µg/mL.
Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Secondary

End point timeframe:

At Day 1 and Day 30

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 1, Day1 (N=12,14,10,22)	80.0 (51.9 to 95.7)	93.3 (68.1 to 99.8)	62.5 (35.4 to 84.8)	75.9 (56.5 to 89.7)
Serotype 1, Day30 (N=14,15,15,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 3, Day1 (N=0,5,4,4)	0 (0.0 to 21.8)	33.3 (11.8 to 61.6)	25.0 (7.3 to 52.4)	13.8 (3.9 to 31.7)
Serotype 3, Day30 (N=14,15,14,26)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	96.3 (81.0 to 99.9)
Serotype 4, Day1 (N=6,8,9,11)	40.0 (16.3 to 67.7)	53.3 (26.6 to 78.7)	56.3 (29.9 to 80.2)	37.9 (20.7 to 57.7)
Serotype 4, Day30 (N=14,15,14,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)
Serotype 5, Day1 (N=8,10,11,15)	53.3 (26.6 to 78.7)	66.7 (38.4 to 88.2)	68.8 (41.3 to 89.0)	51.7 (32.5 to 70.6)
Serotype 5, Day30 (N=13,15,15,27)	92.9 (66.1 to 99.8)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 6A, Day1 (N=14,13,12,23)	93.3 (68.1 to 99.8)	86.7 (59.5 to 98.3)	75.0 (47.6 to 92.7)	79.3 (60.3 to 92.0)
Serotype 6A, Day30 (N=14,15,15,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 6B, Day1 (N=7,10,10,17)	46.7 (21.3 to 73.4)	66.7 (38.4 to 88.2)	62.5 (35.4 to 84.8)	58.6 (38.9 to 76.5)

Serotype 6B, Day30 (N=14,15,15,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 7F, Day1 (N=15,13,14,29)	100.0 (78.2 to 100.0)	86.7 (59.5 to 98.3)	87.5 (61.7 to 98.4)	100.0 (88.1 to 100.0)
Serotype 7F, Day30 (N=14,15,14,28)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)
Serotype 9V, Day1 (N=7,5,8,14)	46.7 (21.3 to 73.4)	33.3 (11.8 to 61.6)	50.0 (24.7 to 75.3)	48.3 (29.4 to 67.5)
Serotype 9V, Day30 (N=14,15,15,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 14, Day1 (N=11,15,14,27)	73.3 (44.9 to 92.2)	100.0 (78.2 to 100.0)	87.5 (61.7 to 98.4)	93.1 (77.2 to 99.2)
Serotype 14, Day30 (N=13,15,14,27)	92.9 (66.1 to 99.8)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)
Serotype 18C, Day1 (N=8,11,11,19)	53.3 (26.6 to 78.7)	73.3 (44.9 to 92.2)	68.8 (41.3 to 89.0)	65.5 (45.7 to 82.1)
Serotype 18C, Day30 (N=13,15,14,27)	92.9 (66.1 to 99.8)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)
Serotype 19A, Day1 (N=3,7,8,15)	20.0 (4.3 to 48.1)	46.7 (21.3 to 73.4)	50.0 (24.7 to 75.3)	51.7 (32.5 to 70.6)
Serotype 19A, Day30 (N=14,15,14,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)
Serotype 19F, Day1 (N=10,10,11,19)	66.7 (38.4 to 88.2)	66.7 (38.4 to 88.2)	68.8 (41.3 to 89.0)	65.5 (45.7 to 82.1)
Serotype 19F, Day30 (N=14,15,15,27)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (87.2 to 100.0)
Serotype 23F, Day1 (N=9,9,11,14)	60.0 (32.3 to 83.7)	60.0 (32.3 to 83.7)	68.8 (41.3 to 89.0)	48.3 (29.4 to 67.5)
Serotype 23F, Day30 (N=13,15,14,27)	92.9 (66.1 to 99.8)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (87.2 to 100.0)

Statistical analyses

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.7
upper limit	27.7

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	17.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.8
upper limit	37.5

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-13.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.4
upper limit	13.7

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-13.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.8
upper limit	8

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	47.1

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	11.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.8
upper limit	38.2

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.4
upper limit	32.1

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15
upper limit	43.7

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.9
upper limit	45.7

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.5
upper limit	30.9

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.2
upper limit	41.8

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	43.1

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.9
upper limit	33.7

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.3
upper limit	28.8

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.3
upper limit	19.8

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.6
upper limit	18.5

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.7
upper limit	35.1

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26
upper limit	31.5

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-13.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.2
upper limit	-0.3

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-12.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.3
upper limit	0.4

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.9
upper limit	28.5

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.8
upper limit	16.2

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-19.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-46.5
upper limit	1.8

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.4
upper limit	22.2

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.4
upper limit	12.5

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-12.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.2
upper limit	17.3

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	7.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.4
upper limit	33.5

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.3
upper limit	29.6

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-31.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55
upper limit	-0.8

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-5.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34.2
upper limit	25.2

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.9
upper limit	27.6

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29
upper limit	28.3

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29
upper limit	28.3

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.3
upper limit	29.6

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.2
upper limit	39.7

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.2
upper limit	39.7

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	20.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	46.3

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.6
upper limit	18.5

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.4
upper limit	18.5

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27
upper limit	13.1

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.9
upper limit	6.2

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.9
upper limit	6.2

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.9
upper limit	6.2

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.9
upper limit	6.2

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13

Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	6.6

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettien and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.6
upper limit	30.9

Secondary: Percentage of Subjects with Serotype-specific Opsonophagocytic Activity (OPA) Antibody Titer >= Lower Limit of Quantification (LLOQ)

End point title	Percentage of Subjects with Serotype-specific Opsonophagocytic Activity (OPA) Antibody Titer >= Lower Limit of Quantification (LLOQ)

End point description:

Immunogenicity was measured in terms of percentage of subjects with OPA Antibody Titer >= LLOQ. Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Secondary

End point timeframe:

At Day 1 and Day 30

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Percentage of subjects				
number (confidence interval 95%)				
Serotype 1, Day1 (N=6,6,10,7)	40.0 (16.3 to 67.7)	46.2 (19.2 to 74.9)	62.5 (35.4 to 84.8)	25.0 (10.7 to 44.9)
Serotype 1, Day30 (N=11,13,12,26)	78.6 (49.2 to 95.3)	100.0 (75.3 to 100.0)	92.3 (64.0 to 99.8)	100.0 (86.8 to 100.0)
Serotype 3, Day1 (N=14,13,16,27)	93.3 (68.1 to 99.8)	100.0 (75.3 to 100.0)	100.0 (79.4 to 100.0)	96.4 (81.7 to 99.9)
Serotype 3, Day30 (N=13,15,14,25)	100.0 (75.3 to 100.0)	100.0 (78.2 to 100.0)	100.0 (76.8 to 100.0)	100.0 (86.3 to 100.0)
Serotype 4, Day1 (N=10,9,14,22)	71.4 (41.9 to 91.6)	75.0 (42.8 to 94.5)	87.5 (61.7 to 98.4)	78.6 (59.0 to 91.7)
Serotype 4, Day30 (N=12,15,15,25)	100.0 (73.5 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (86.3 to 100.0)
Serotype 5, Day1 (N=13,12,15,24)	100.0 (75.3 to 100.0)	85.7 (57.2 to 98.2)	93.8 (69.8 to 99.8)	82.8 (64.2 to 94.2)
Serotype 5, Day30 (N=14,14,12,25)	100.0 (76.8 to 100.0)	100.0 (76.8 to 100.0)	100.0 (73.5 to 100.0)	100.0 (86.3 to 100.0)
Serotype 6A, Day1 (N=13,13,15,28)	100.0 (75.3 to 100.0)	92.9 (66.1 to 99.8)	93.8 (69.8 to 99.8)	96.6 (82.2 to 99.9)
Serotype 6A, Day30 (N=14,15,15,24)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (85.8 to 100.0)
Serotype 6B, Day1 (N=13,12,13,21)	86.7 (59.5 to 98.3)	85.7 (57.2 to 98.2)	81.3 (54.4 to 96.0)	77.8 (57.7 to 91.4)
Serotype 6B, Day30 (N=13,15,15,25)	100.0 (75.3 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (86.3 to 100.0)
Serotype 7F, Day1 (N=15,14,16,29)	100.0 (78.2 to 100.0)	100.0 (76.8 to 100.0)	100.0 (79.4 to 100.0)	100.0 (88.1 to 100.0)
Serotype 7F, Day30 (N=11,15,15,22)	100.0 (71.5 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (84.6 to 100.0)
Serotype 9V, Day1 (12,10,14,21)	100.0 (73.5 to 100.0)	83.3 (51.6 to 97.9)	93.3 (68.1 to 99.8)	91.3 (72.0 to 98.9)
Serotype 9V, Day30 (N=12,13,15,24)	100.0 (73.5 to 100.0)	100.0 (75.3 to 100.0)	100.0 (78.2 to 100.0)	100.0 (85.8 to 100.0)
Serotype 14, Day1 (12,14,15,25)	85.7 (57.2 to 98.2)	100.0 (76.8 to 100.0)	93.8 (69.8 to 99.8)	92.6 (75.7 to 99.1)
Serotype 14, Day30 (N=12,15,14,24)	92.3 (64.0 to 99.8)	100.0 (78.2 to 100.0)	93.3 (68.1 to 99.8)	100.0 (85.8 to 100.0)
Serotype 18C, Day1 (N=14,10,14,24)	100.0 (76.8 to 100.0)	83.3 (51.6 to 97.9)	87.5 (61.7 to 98.4)	85.7 (67.3 to 96.0)
Serotype 18C, Day30 (N=11,15,15,25)	100.0 (71.5 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (86.3 to 100.0)
Serotype 19A, Day1 (N=12,13,15,24)	85.7 (57.2 to 98.2)	100.0 (75.3 to 100.0)	93.8 (69.8 to 99.8)	85.7 (67.3 to 96.0)
Serotype 19A, Day30 (N=14,15,15,26)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (86.8 to 100.0)
Serotype 19F, Day1 (N=11,12,14,22)	100.0 (71.5 to 100.0)	85.7 (57.2 to 98.2)	87.5 (61.7 to 98.4)	81.5 (61.9 to 93.7)
Serotype 19F, Day30 (N=14,14,15,23)	100.0 (76.8 to 100.0)	100.0 (76.8 to 100.0)	100.0 (78.2 to 100.0)	100.0 (85.2 to 100.0)
Serotype 23F, Day1 (N=15,12,16,26)	100.0 (78.2 to 100.0)	100.0 (73.5 to 100.0)	100.0 (79.4 to 100.0)	89.7 (72.6 to 97.8)
Serotype 23F, Day30 (N=13,15,15,23)	100.0 (75.3 to 100.0)	100.0 (78.2 to 100.0)	100.0 (78.2 to 100.0)	100.0 (85.2 to 100.0)

Statistical analyses

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.2
upper limit	43.7

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	21.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	50.5

Statistical analysis title	Serotype 1, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	37.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	62.1

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.1
upper limit	12.5

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20
upper limit	18

Statistical analysis title	Serotype 3, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.4
upper limit	18

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-36.9
upper limit	18.7

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.3
upper limit	22

Statistical analysis title	Serotype 4, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	8.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.9
upper limit	30.5

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	17.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.3
upper limit	34.8

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	24.3

Statistical analysis title	Serotype 5, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	11

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	30.1

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.1
upper limit	17.4

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.8
upper limit	11.7

Statistical analysis title	Serotype 6A, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-2.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.7
upper limit	12.3

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	8.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.1
upper limit	31.2

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	7.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.2
upper limit	30.6

Statistical analysis title	Serotype 6B, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Post-hoc
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	3.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.4
upper limit	27

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.9
upper limit	27.1

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38
upper limit	14.6

Statistical analysis title	Serotype 9V, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.8
upper limit	21.9

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Group 3, ASP3772 High Dose
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-34
upper limit	12.7

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	23.6

Statistical analysis title	Serotype 14, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	1.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.3
upper limit	18.7

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	14.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.8
upper limit	31.7

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.9
upper limit	19.7

Statistical analysis title	Serotype 18C, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	1.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.1
upper limit	22.3

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28
upper limit	21.2

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	14.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	31.7

Statistical analysis title	Serotype 19A, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.2
upper limit	27

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	18.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.4
upper limit	37

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.4
upper limit	26.5

Statistical analysis title	Serotype 19F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.5
upper limit	27.6

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	10.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.2
upper limit	26.6

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-21.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.9
upper limit	-6.5

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 1, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.7
upper limit	6.2

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 3, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 4, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 5, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6A, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 6B, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 7F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 9V, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.8
upper limit	7.2

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 14, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	-6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.2
upper limit	8

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 18C, Day 30
Comparison groups	Comparator PCV13 v Group 3, ASP3772 High Dose
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19A, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 19F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 1, ASP3772 Low Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0

Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 30
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	0
upper limit	0

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 2, ASP3772 Medium Dose v Comparator PCV13
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	10.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	26.6

Statistical analysis title	Serotype 23F, Day 1
Comparison groups	Group 3, ASP3772 High Dose v Comparator PCV13
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	other
Method	Miettinen and Nurminen
Parameter estimate	Difference in proportion
Point estimate	10.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.1
upper limit	26.6

Secondary: Geometric Mean Titer (GMT) for Serotype-specific OPA

End point title	Geometric Mean Titer (GMT) for Serotype-specific OPA

End point description:

Immunogenicity was measured in terms of OPA GMTs and expressed as titers.
Analysis was performed on SAF which consisted of all randomized subjects who received a vaccination in this study with either ASP3772 or PCV13, per treatment actually received.

End point type	Secondary

End point timeframe:

At Day 1 and Day 30

End point values	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose	Comparator PCV13
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	16	29
Units: Titers				
geometric mean (confidence interval 95%)				
Serotype 1, Day1 (N=15,13,16,28)	10.2 (5.7 to 18.2)	15.9 (6.5 to 39.4)	20.7 (9.9 to 42.9)	10.1 (6.0 to 17.3)
Serotype 1, Day30 (N=14,13,13,26)	54.7 (21.0 to 142.4)	170.5 (67.2 to 432.1)	172.8 (70.3 to 424.8)	188.6 (120.5 to 295.1)
Serotype 3, Day1 (N=15,13,16,28)	55.4 (32.8 to 93.4)	101.7 (51.8 to 199.7)	118.4 (70.2 to 199.8)	125.0 (81.9 to 191.0)
Serotype 3, Day30 (N=13,15,14,25)	339.1 (273.6 to 420.1)	467.1 (318.1 to 686.1)	692.5 (386.3 to 1241.4)	450.1 (338.4 to 598.6)
Serotype 4, Day1 (N=14,12,16,28)	32.6 (11.6 to 91.3)	83.9 (24.2 to 290.7)	130.4 (46.9 to 363.2)	51.5 (26.2 to 101.4)
Serotype 4, Day30 (N=12,15,15,25)	427.5 (230.2 to 794.0)	1142.5 (725.1 to 1800.1)	1071.8 (541.2 to 2122.6)	2217.0 (1685.4 to 2916.3)
Serotype 5, Day1 (N=13,14,16,29)	119.0 (76.9 to 184.1)	158.2 (48.0 to 521.3)	192.5 (81.3 to 455.9)	52.9 (28.4 to 98.5)
Serotype 5, Day30 (N=14,14,12,25)	694.4 (336.7 to 1432.1)	978.1 (385.3 to 2483.2)	984.3 (410.9 to 2357.7)	797.8 (503.7 to 1263.5)
Serotype 6A, Day1 (N=13,14,16,29)	1664.2 (1005.7 to 2753.9)	983.7 (402.5 to 2404.3)	938.2 (373.1 to 2359.5)	816.7 (490.6 to 1359.6)
Serotype 6A, Day30 (N=14,15,15,24)	2790.1 (1995.2 to 3901.6)	3312.4 (2221.4 to 4939.3)	2471.5 (1219.7 to 5008.1)	9502.0 (6137.0 to 14712.1)
Serotype 6B, Day1 (N=15,14,16,27)	412.3 (148.9 to 1141.1)	241.4 (82.3 to 707.8)	236.2 (73.0 to 764.9)	150.5 (65.3 to 347.1)
Serotype 6B, Day30 (N=13,15,15,25)	1955.8 (1128.5 to 3389.3)	1489.5 (999.2 to 2220.6)	1387.4 (582.6 to 3304.3)	5134.9 (3428.0 to 7691.9)

Serotype 7F, Day1 (N=15,14,16,29)	1409.4 (829.6 to 2394.6)	1075.6 (526.7 to 2196.3)	1077.1 (640.3 to 1811.7)	1436.1 (1003.0 to 2056.3)
Serotype 7F, Day30 (N=11,15,15,22)	2326.1 (1260.9 to 4291.2)	2615.8 (1539.4 to 4444.9)	2563.5 (1338.0 to 4911.3)	8442.5 (4987.7 to 14290.3)
Serotype 9V, Day1 (N=12,12,15,23)	2311.2 (872.7 to 6120.6)	360.7 (60.3 to 2158.4)	602.2 (219.2 to 1654.6)	345.0 (134.4 to 885.3)
Serotype 9V, Day30 (N=12,13,15,24)	4080.3 (2654.5 to 6271.9)	3636.3 (1908.0 to 6930.2)	2347.9 (1429.3 to 3856.9)	5142.6 (3544.9 to 7460.3)
Serotype 14, Day1 (N=14,14,16,27)	259.6 (90.5 to 744.6)	650.6 (302.7 to 1398.2)	489.4 (187.5 to 1277.7)	476.8 (270.1 to 841.7)
Serotype 14, Day30 (N=13,15,15,24)	556.9 (201.3 to 1540.8)	1842.4 (1124.2 to 3019.6)	1090.4 (440.0 to 2702.7)	2922.4 (1985.7 to 4300.8)
Serotype 18C, Day1 (N=14,12,16,28)	249.4 (93.6 to 664.9)	267.4 (67.3 to 1061.6)	276.6 (105.2 to 726.8)	229.4 (118.6 to 443.6)
Serotype 18C, Day30 (N=11,15,15,25)	1481.9 (935.7 to 2347.0)	1772.6 (1132.9 to 2773.4)	1935.4 (1042.9 to 3591.9)	5268.2 (3876.1 to 7160.3)
Serotype 19A, Day1 (N=14,13,16,28)	177.7 (59.9 to 526.6)	241.8 (80.3 to 728.1)	320.0 (137.5 to 744.7)	176.3 (88.6 to 350.6)
Serotype 19A, Day30 (N=14,15,15,26)	1851.6 (1055.9 to 3246.7)	2621.7 (1802.2 to 3813.8)	1919.7 (1040.0 to 3543.5)	5801.8 (4546.2 to 7404.1)
Serotype 19F, Day1 (N=11,14,16,27)	373.2 (175.9 to 791.9)	326.3 (97.5 to 1091.4)	315.6 (118.1 to 843.4)	230.3 (111.0 to 477.7)
Serotype 19F, Day30 (N=14,14,15,23)	1998.7 (1328.7 to 3006.4)	2601.4 (1776.3 to 3809.6)	2704.6 (1412.0 to 5180.5)	4678.9 (3559.7 to 6150.1)
Serotype 23F, Day1 (N=15,12,16,29)	760.1 (310.7 to 1859.1)	766.4 (260.2 to 2257.6)	1005.8 (423.8 to 2386.8)	410.5 (189.4 to 889.5)
Serotype 23F, Day30 (N=13,15,15,23)	1711.8 (1118.0 to 2620.9)	1702.5 (1104.1 to 2625.3)	3462.8 (1320.2 to 9082.4)	12510.5 (7488.7 to 20900.0)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: SAEs were collected from Day 1 to Day 180 (study end). Non-serious adverse events were collected from Day 1 to Day 30.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Group 1, ASP3772 Low Dose
Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single intramuscular (IM) injection of low dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 2, ASP3772 Medium Dose
Reporting group description: Healthy toddlers approximately 12 to 15 months received a single IM injection of medium dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	Group 3, ASP3772 High Dose
Reporting group description: Healthy toddlers approximately 12 to 15 months received a single IM injection of high dose of ASP3772 into anterolateral right or left thigh muscle on Day 1.	
Reporting group title	PCV13 Comparator
Reporting group description: Healthy toddlers aged approximately 12 to 15 months received a single IM injection of approved dose of PCV13 into anterolateral right or left thigh muscle on Day 1.	

Serious adverse events	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	PCV13 Comparator		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 29 (6.90%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Seizure			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Group 1, ASP3772 Low Dose	Group 2, ASP3772 Medium Dose	Group 3, ASP3772 High Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 15 (26.67%)	4 / 15 (26.67%)	9 / 16 (56.25%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	1 / 16 (6.25%)
occurrences (all)	1	1	1

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	2 / 16 (12.50%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	1 / 16 (6.25%)
occurrences (all)	0	1	1
Teething			
subjects affected / exposed	1 / 15 (6.67%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	1	1	0
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Vomiting projectile			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	2 / 15 (13.33%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	2	1	0
Cough			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Dermatitis diaper			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Irritability			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Croup infectious			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 15 (0.00%)	1 / 15 (6.67%)	0 / 16 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 15 (0.00%)	0 / 16 (0.00%)
occurrences (all)	1	0	0
Ear infection			

subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	1 / 16 (6.25%)
occurrences (all)	0	0	1

Non-serious adverse events	PCV13 Comparator		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 29 (31.03%)		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Thermal burn			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Teething			
subjects affected / exposed	2 / 29 (6.90%)		
occurrences (all)	2		
Flatulence			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Vomiting projectile			

subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Wheezing subjects affected / exposed occurrences (all)	 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all) Dermatitis diaper subjects affected / exposed occurrences (all)	 0 / 29 (0.00%) 0 2 / 29 (6.90%) 2		
Psychiatric disorders Irritability subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all)	 1 / 29 (3.45%) 1 2 / 29 (6.90%) 2		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Croup infectious subjects affected / exposed occurrences (all) Gastroenteritis viral subjects affected / exposed occurrences (all)	 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0 0 / 29 (0.00%) 0		

Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Otitis media acute			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	1 / 29 (3.45%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	0 / 29 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 February 2020	• The objectives were reorganized such that comparison of the GMT for functional OPA for each serotype post-vaccination was moved from the exploratory to the secondary list of objectives. • The list of exclusion criteria was updated to include the exclusion of subjects who had previously received an approved (other than PCV13) or investigational pneumococcal vaccine.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported