



Clinical trial results:

Pneumococcal Vaccination to Accelerate Immune Recovery in Sepsis Survivors: randomized placebo-controlled trial

Summary

EudraCT number	2017-002236-17
Trial protocol	GB
Global end of trial date	31 August 2023

Results information

Result version number	v1 (current)
This version publication date	25 March 2026
First version publication date	25 March 2026
Summary attachment (see zip file)	VACIRISS Clinical Study Report_15Oct25 (VACIRISS Clinical Study Report_v1.0_15Oct25.pdf)

Trial information

Trial identification

Sponsor protocol code	VACIRISS
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE1 9RT
Public contact	Dr Manu Shankar-Hari , Guy's and St Thomas' NHS Foundation Trust , 44 0207188 3044, manu.shankar-hari@gstt.nhs.uk
Scientific contact	Dr Manu Shankar-Hari , Guy's and St Thomas' NHS Foundation Trust , 44 0207188 3044, manu.shankar-hari@gstt.nhs.uk

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 April 2023
Global end of trial reached?	Yes
Global end of trial date	31 August 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the hazard ratio for infection related rehospitalisation or death within the 365-day follow-up period between intervention and control arm.

Protection of trial subjects:

Participants have the right to withdraw from the study at any time for any reason.

The investigator also has the right to withdraw patients from the study drug in the event of intercurrent illness, AEs, SAE's, SUSAR's, protocol violations, cure, administrative reasons or other reasons.

It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretable; therefore, unnecessary withdrawal of patients should be avoided. Withdrawn patients will not be replaced with new recruitment.

Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

After initial vaccination, there is no ongoing trial medication (IMP), only follow-up visits. The trial team will use already collected clinical data and biological samples.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2018
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 Kingdom: 214
Worldwide total number of subjects	214
EEA total number of subjects	214

Notes:

Subjects enrolled per age group

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

Adolescents (12-17 years)	0
Adults (18-64 years)	120
From 65 to 84 years	94
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	214
Number of subjects completed	214

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo
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Arm description: -

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

Dosage and administration details:

Equivalent volume (0.5mls) of sodium chloride
0.9% as placebo intervention

Arm title	Investigational Arm
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Pneumococcal polysaccharide conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pneumococcal polysaccharide conjugate
vaccine (13-valent, adsorbed) [PCV13], single
dose (0.5mls), intra muscular

Number of subjects in period 1	Placebo	Investigational Arm
Started	110	104
Completed	109	103
Not completed	1	1
Withdrawn on day of randomization	1	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Investigational Arm
Reporting group description: -	

Reporting group values	Placebo	Investigational Arm	Total
Number of subjects	110	104	214
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	59.9	60.5	
standard deviation	± 14.2	± 15	-
Gender categorical Units: Subjects			
Female	43	48	91
Male	67	56	123

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Investigational Arm
Reporting group description: -	

Primary: Time of first infection-related rehospitalisation or death

End point title	Time of first infection-related rehospitalisation or death ^[1]
End point description:	

End point type	Primary
End point timeframe:	
Within the 365 days follow-up period	

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: Please see uploaded report

End point values	Placebo	Investigational Arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	109	103		
Units: Person-years				
arithmetic mean (standard deviation)	76.5 (\pm 0.50)	72.5 (\pm 0.59)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to 365 days follow-up period

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	21.1
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Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	PCV13
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Reporting group description: -

Serious adverse events	Placebo	PCV13	
Total subjects affected by serious adverse events			
subjects affected / exposed	69 / 109 (63.30%)	103 / 103 (100.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			

subjects affected / exposed	0 / 109 (0.00%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Abscess drainage			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aneurysm repair			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder catheter removal			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery surgery			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Debridement			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hospitalisation			
subjects affected / exposed	0 / 109 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrectomy			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic pseudocyst drainage			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheal lesion excision			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 109 (0.92%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeding tube complication			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothermia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 109 (0.00%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chest pain			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 109 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusion			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Prostate examination			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site pain			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	2 / 109 (1.83%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip Fracture			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Post procedural complication subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute pulmonary oedema subjects affected / exposed	2 / 109 (1.83%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachyarrhythmia			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 109 (0.92%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 109 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wound dehiscence			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hiatus hernia			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis chronic			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis necrotising			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			

subjects affected / exposed	0 / 109 (0.00%)	4 / 103 (3.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Decubitis ulcer			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic foot infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hidradenitis			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Chronic kidney disease			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacteria			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Atypical pneumonia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 109 (1.83%)	4 / 103 (3.88%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emphysematous cystitis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	2 / 109 (1.83%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	3 / 109 (2.75%)	5 / 103 (4.85%)	
occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	8 / 109 (7.34%)	6 / 103 (5.83%)	
occurrences causally related to treatment / all	0 / 8	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	2 / 109 (1.83%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudoaneurysm infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	2 / 109 (1.83%)	3 / 103 (2.91%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 109 (1.83%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 1	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Electrolyte imbalance			
subjects affected / exposed	0 / 109 (0.00%)	2 / 103 (1.94%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeding intolerance			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	PCV13	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	55 / 109 (50.46%)	41 / 103 (39.81%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bartholin's cyst			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Surgical and medical procedures			
Enterostomy			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Hospitalisation			

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Immunisation subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
General disorders and administration site conditions			
Impaired healing subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Injection site pain subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Joint range of motion decreased subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	0 / 103 (0.00%) 0	
Pyrexia subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	1 / 103 (0.97%) 1	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Dyspnoea subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Psychiatric disorders			
Mood altered subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Investigations			
Ureteroscopy subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Injury, poisoning and procedural complications			

Fall subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	1 / 103 (0.97%) 1	
Nervous system disorders Bell's palsy subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Headache subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	0 / 103 (0.00%) 0	
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Diarrhoea subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Taste disorder subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Vomiting subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Actinic keratosis subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Skin ulcer subjects affected / exposed occurrences (all)	2 / 109 (1.83%) 2	0 / 103 (0.00%) 0	
Musculoskeletal and connective tissue			

disorders			
Myalgia			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences (all)	1	1	
Infections and infestations			
Biliary sepsis			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Cellulitis			
subjects affected / exposed	2 / 109 (1.83%)	1 / 103 (0.97%)	
occurrences (all)	2	1	
Ear infection			
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)	
occurrences (all)	1	1	
Epididymitis			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Gastrointestinal infection			
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)	
occurrences (all)	0	1	
Genitourinary tract infection			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Herpes zoster			
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)	
occurrences (all)	1	0	
Infected bite			
subjects affected / exposed	2 / 109 (1.83%)	0 / 103 (0.00%)	
occurrences (all)	2	0	
Infection			
subjects affected / exposed	2 / 109 (1.83%)	3 / 103 (2.91%)	
occurrences (all)	3	6	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	2 / 109 (1.83%)	0 / 103 (0.00%)
occurrences (all)	6	0
Localised infection		
subjects affected / exposed	2 / 109 (1.83%)	5 / 103 (4.85%)
occurrences (all)	2	5
Lower respiratory tract infection		
subjects affected / exposed	6 / 109 (5.50%)	4 / 103 (3.88%)
occurrences (all)	7	7
Mycoplasma infection		
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)
occurrences (all)	1	0
Oral infection		
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Pharyngitis		
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)
occurrences (all)	1	0
Pneumonia		
subjects affected / exposed	0 / 109 (0.00%)	3 / 103 (2.91%)
occurrences (all)	0	3
Respiratory tract infection		
subjects affected / exposed	2 / 109 (1.83%)	1 / 103 (0.97%)
occurrences (all)	3	1
Tonsillitis		
subjects affected / exposed	1 / 109 (0.92%)	1 / 103 (0.97%)
occurrences (all)	1	1
Tracheostomy infection		
subjects affected / exposed	1 / 109 (0.92%)	0 / 103 (0.00%)
occurrences (all)	1	0
Upper respiratory tract infection		
subjects affected / exposed	0 / 109 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	1
Urinary tract infection		
subjects affected / exposed	4 / 109 (3.67%)	7 / 103 (6.80%)
occurrences (all)	10	7
Vascular device infection		

subjects affected / exposed occurrences (all)	0 / 109 (0.00%) 0	1 / 103 (0.97%) 1	
Wound infection subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Metabolism and nutrition disorders			
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	
Malnutrition subjects affected / exposed occurrences (all)	1 / 109 (0.92%) 1	0 / 103 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 May 2018	Protocol v2.0 - Changes to the Exclusion criteria, pre-screening and pre-screening log and minor administrative changes and clarifications throughout
27 July 2018	Protocol v3.0 - PIS and protocol changes
22 November 2018	Protocol v4.0 - Changes to informed consent, IMP administration, number of sites and various minor administrative changes and clarifications throughout
27 February 2019	Protocol v5.0 - PIS and protocol changes
26 June 2019	Protocol v6.0 - PIS, Lab manual and Protocol changes
22 February 2021	Protocol v6.1 - Changes to PIS, GP letter and changes to sites
01 November 2021	Protocol v6.2 - Change in location of the Chief Investigators lab

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported