Clinical trial results:
Using BCG vaccine to strengthen the immune system in the elderly and improve the response to influenza vaccine. A randomized clinical trial.

Summary

EudraCT number	2019-002781-12
Trial protocol	DK
Global end of trial date	05 July 2022

Results information

Result version number	v1 (current)
This version publication date	16 October 2024
First version publication date	16 October 2024

Trial information

Trial identification

Sponsor protocol code	2019061567

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Southern Denmark, Bandim Health Project
Sponsor organisation address	Studiestræde 6, København K, Denmark, 1455
Public contact	Christine Stabell Benn, Bandim Health Project, cbenn@health.sdu.dk
Scientific contact	Christine Stabell Benn, Bandim Health Project, cbenn@health.sdu.dk

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	05 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 July 2022
Global end of trial reached?	Yes
Global end of trial date	05 July 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

We tested the effect of BCG vaccine on the specific immune response to seasonal influenza vaccination in elderly people>65 years, with the aim to improve the specific antibody response to the vaccination.

Protection of trial subjects:

Participants were instructed to report (serious) adverse events in biweekly questionnaires during the six months of follow-up but were also encouraged to contact study personnel directly in case of suspected adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 273
Worldwide total number of subjects	273
EEA total number of subjects	273

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)	0
From 65 to 84 years	272
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Recruitment took place from October to November 2021 in Odense, a Danish city of approximately 200,000 inhabitants. Citizens aged 65 years or older, who were eligible for seasonal influenza vaccination, were recruited. Exclusion criteria were known contraindications to BCG and/or influenza vaccination.

Pre-assignment

Screening details:

We screened 284 individuals for eligibility. Eleven persons did not meet inclusion criteria or declined to participate. In total, 273 individuals were included and randomised to four groups: group 1 (N=67), group 2 (N=69), group 3 (N=67) and group 4 (N=70).

Pre-assignment period milestones

Number of subjects started	273
Number of subjects completed	273

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1

Arm description:

Group 1 were vaccinated with BCG at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.

Arm type	Experimental
Investigational medicinal product name	BCG vaccine, AJ Vaccines, Denmark
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Intradermal injection of 0.1 ml of suspended vaccine. After reconstitution, one dose (0.1 ml) contains live attenuated Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, 2-8 x 10_5 cfu.

Investigational medicinal product name	Influvactetra, Mylan ApS, Denmark
Investigational medicinal product code	31398
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

All participants received the standard dose inactivated influenza vaccine as recommended by the Danish Board of Health for the season of 2021/2022. One dose of the quadrivalent vaccine (Influvactetra) was given by intramuscular injection of 0.5 ml vaccine suspension in the deltoid area of the left arm.

Investigational medicinal product name	Sterile 0.9% Sodium Chloride solution
Investigational medicinal product code	
Other name	Saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Placebo constituted 0.1 ml of sterile sodium chloride solution (saline) injected in the same way as the real vaccine.

Arm title	Group 2

Arm description:

Group 2 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.

Arm type	Active comparator
Investigational medicinal product name	Influvactetra, Mylan ApS, Denmark
Investigational medicinal product code	31398
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

All participants received the standard dose inactivated influenza vaccine as recommended by the Danish Board of Health for the season of 2021/2022. One dose of the quadrivalent vaccine (Influvactetra) was given by intramuscular injection of 0.5 ml vaccine suspension in the deltoid area of the left arm.

Investigational medicinal product name	Sterile 0.9% Sodium Chloride solution
Investigational medicinal product code	
Other name	Saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Placebo constituted 0.1 ml of sterile sodium chloride solution (saline) injected in the same way as the real vaccine.

Arm title	Group 3

Arm description:

Group 3 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of BCG vaccine by intradermal injection in the deltoid area of the right arm.

Arm type	Experimental
Investigational medicinal product name	BCG vaccine, AJ Vaccines, Denmark
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Intradermal injection of 0.1 ml of suspended vaccine. After reconstitution, one dose (0.1 ml) contains live attenuated Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, 2-8 x 10_5 cfu.

Investigational medicinal product name	Influvactetra, Mylan ApS, Denmark
Investigational medicinal product code	31398
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

All participants received the standard dose inactivated influenza vaccine as recommended by the Danish

Board of Health for the season of 2021/2022. One dose of the quadrivalent vaccine (Influvactetra) was given by intramuscular injection of 0.5 ml vaccine suspension in the deltoid area of the left arm.

Investigational medicinal product name	Sterile 0.9% Sodium Chloride solution
Investigational medicinal product code	
Other name	Saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Placebo constituted 0.1 ml of sterile sodium chloride solution (saline) injected in the same way as the real vaccine.

Arm title	Group 4

Arm description:

Group 4 were vaccinated with a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm at inclusion (day 0). At day 14, they were vaccinated with BCG by intradermal injection in the deltoid area of the right arm and received a dose of placebo by intramuscular injection in the deltoid area of the left arm.

Arm type	Experimental
Investigational medicinal product name	Influvactetra, Mylan ApS, Denmark
Investigational medicinal product code	31398
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

All participants received the standard dose inactivated influenza vaccine as recommended by the Danish Board of Health for the season of 2021/2022. One dose of the quadrivalent vaccine (Influvactetra) was given by intramuscular injection of 0.5 ml vaccine suspension in the deltoid area of the left arm.

Investigational medicinal product name	BCG vaccine, AJ Vaccines, Denmark
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Intradermal injection of 0.1 ml of suspended vaccine. After reconstitution, one dose (0.1 ml) contains live attenuated Mycobacterium bovis BCG (Bacillus Calmette-Guerin), Danish strain 1331, 2-8 x 10_5 cfu.

Investigational medicinal product name	Sterile 0.9% Sodium Chloride solution
Investigational medicinal product code	
Other name	Saline
Pharmaceutical forms	Solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

Placebo constituted 0.1 ml of sterile sodium chloride solution (saline) injected in the same way as the real vaccine.

Number of subjects in period 1	Group 1	Group 2	Group 3
Started	67	69	67
Completed	66	67	65
Not completed	1	2	2
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	1	1	-

Protocol deviation	-	-	2

Number of subjects in period 1	Group 4
Started	70
Completed	68
Not completed	2
Adverse event, serious fatal	-
Consent withdrawn by subject	1
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Group 1
Reporting group description:	
Group 1 were vaccinated with BCG at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.	
Reporting group title	Group 2
Reporting group description:	
Group 2 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.	
Reporting group title	Group 3
Reporting group description:	
Group 3 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of BCG vaccine by intradermal injection in the deltoid area of the right arm.	
Reporting group title	Group 4
Reporting group description:	
Group 4 were vaccinated with a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm at inclusion (day 0). At day 14, they were vaccinated with BCG by intradermal injection in the deltoid area of the right arm and received a dose of placebo by intramuscular injection in the deltoid area of the left arm.	

Reporting group values	Group 1	Group 2	Group 3
Number of subjects	67	69	67
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	67	69	67
85 years and over	0	0	0
Age continuous Units: years			
median	70.6	70.5	69.2
inter-quartile range (Q1-Q3)	67.9 to 74.4	67.5 to 74.5	66.9 to 74.5
Gender categorical Units: Subjects			
Female	30	32	30
Male	37	37	37

Previous influenza vaccination Units: Subjects			
Yes	62	60	58
No	5	9	9
Vaccinated against COVID-19 Units: Subjects			
Yes	67	69	66
No	0	0	1

Reporting group values	Group 4	Total	
Number of subjects	70	273	
Age categorical 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)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	69	272	
85 years and over	1	1	
Age continuous Units: years			
median	70.6		
inter-quartile range (Q1-Q3)	68.4 to 75.5	-	
Gender categorical Units: Subjects			
Female	32	124	
Male	38	149	
Previous influenza vaccination Units: Subjects			
Yes	69	249	
No	1	24	
Vaccinated against COVID-19 Units: Subjects			
Yes	69	271	
No	1	2	

End points

End points reporting groups

Reporting group title	Group 1

Reporting group description:

Group 1 were vaccinated with BCG at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.

Reporting group title	Group 2

Reporting group description:

Group 2 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of placebo in the right arm, given by intradermal injection.

Reporting group title	Group 3

Reporting group description:

Group 3 received placebo at inclusion (day 0) by intradermal injection in the deltoid area of the right arm. At day 14, they received a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm and a dose of BCG vaccine by intradermal injection in the deltoid area of the right arm.

Reporting group title	Group 4

Reporting group description:

Group 4 were vaccinated with a standard dose of inactivated influenza vaccine by intramuscular injection in the deltoid area of the left arm at inclusion (day 0). At day 14, they were vaccinated with BCG by intradermal injection in the deltoid area of the right arm and received a dose of placebo by intramuscular injection in the deltoid area of the left arm.

Primary: Influenza antibody titre after vaccination

End point title	Influenza antibody titre after vaccination

End point description:

Antibody titre HI GMT after vaccination. Change in GMT from before vs after vaccination is compared between treatment groups and the control group.

End point type	Primary

End point timeframe:

Antibody titre 4 weeks after vaccination (for group 4 it is 6 weeks after vaccination).

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	69	65	68
Units: Antibody GMT				
geometric mean (standard deviation)	38.3 (± 2.0)	41.4 (± 1.8)	42.2 (± 2.0)	34.8 (± 1.8)

Statistical analyses

Statistical analysis title	Change in influenza antibody GMT
Statistical analysis description:	
Group 1 and 3 were compared with the control group (group 2) in linear regression adjusted for sex, age group, and baseline antibody level (at day 14 before vaccination).	
Comparison groups	Group 1 v Group 2 v Group 3
Number of subjects included in analysis	201
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Regression, Linear
Parameter estimate	Mean difference (net)
Confidence interval	
level	95 %
sides	1-sided

Secondary: Self-reported infection

End point title	Self-reported infection
End point description:	
Infections reported by participants in biweekly surveys. Infection rate was comared between treatment groups and control group (group 2).	
End point type	Secondary
End point timeframe:	
Within 6 months follow-up	

End point values	Group 1	Group 2	Group 3	Group 4
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	69	67	70
Units: Incidence rate/100 pyrs				
number (not applicable)	224.3	201.8	193.4	211.9

Statistical analyses

Statistical analysis title	Self-reported infections
Statistical analysis description:	
Treatment groups were compared with the control group Anderson-Gill Cox regression model with time since inclusion as underlying time scale. The analysis was adjusted for sex and age group	
Comparison groups	Group 1 v Group 2 v Group 3 v Group 4
Number of subjects included in analysis	273
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Anderson-Gill Cox
Parameter estimate	Hazard ratio (HR)

Confidence interval	
level	95 %
sides	1-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Six months follow-up.	
Adverse event reporting additional description:	
Adverse events were registered within 4 weeks of inclusion, serious adverse events until end of trial. participants could report adverse events via the biweekly questionnaires or directly to the primary investigator at all times during the trial.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Reporting groups	
Reporting group title	Group 1
Reporting group description: -	
Reporting group title	Group 2 (control)
Reporting group description: -	
Reporting group title	Group 3
Reporting group description: -	
Reporting group title	Group 4
Reporting group description: -	

Serious adverse events	Group 1	Group 2 (control)	Group 3
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 67 (5.97%)	5 / 69 (7.25%)	3 / 67 (4.48%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular disorders			
Transient cerebral ischemia			

subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 67 (0.00%)	0 / 69 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Pneumothorax			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	1 / 67 (1.49%)	0 / 69 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 67 (0.00%)	0 / 69 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Fracture			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Wound infection			

subjects affected / exposed	0 / 67 (0.00%)	0 / 69 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 4		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 70 (4.29%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic carcinoma			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic cancer			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Transient cerebral ischemia			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Pneumothorax			

subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Fracture			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Wound infection			
subjects affected / exposed	1 / 70 (1.43%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Group 1	Group 2 (control)	Group 3
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 67 (47.76%)	3 / 69 (4.35%)	26 / 67 (38.81%)
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 67 (13.43%)	1 / 69 (1.45%)	5 / 67 (7.46%)
occurrences (all)	9	1	5
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	7 / 67 (10.45%)	1 / 69 (1.45%)	3 / 67 (4.48%)
occurrences (all)	7	1	3
Lymph node palpable			
subjects affected / exposed	3 / 67 (4.48%)	0 / 69 (0.00%)	3 / 67 (4.48%)
occurrences (all)	3	0	3
Pain at injection site			
subjects affected / exposed	13 / 67 (19.40%)	0 / 69 (0.00%)	13 / 67 (19.40%)
occurrences (all)	13	0	13
Infections and infestations			
Fever			
subjects affected / exposed	0 / 67 (0.00%)	1 / 69 (1.45%)	2 / 67 (2.99%)
occurrences (all)	0	1	2

Non-serious adverse events	Group 4		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 70 (35.71%)		
Nervous system disorders			
Headache			
subjects affected / exposed	9 / 70 (12.86%)		
occurrences (all)	9		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 70 (8.57%)		
occurrences (all)	6		
Lymph node palpable			
subjects affected / exposed	0 / 70 (0.00%)		
occurrences (all)	0		
Pain at injection site			
subjects affected / exposed	8 / 70 (11.43%)		
occurrences (all)	8		
Infections and infestations			
Fever			
subjects affected / exposed	2 / 70 (2.86%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported