Clinical trial results:
Immunization of immunosuppressed patients – Knowledge, practices and serological response

Summary

EudraCT number	2016-004123-23
Trial protocol	DK
Global end of trial date	19 March 2021

Results information

Result version number	v1 (current)
This version publication date	24 June 2022
First version publication date	24 June 2022

Trial information

Trial identification

Sponsor protocol code	Immunovax_Renal

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Infectious Diseases, Odense University Hospital, Odense, Denmark
Sponsor organisation address	J. B. Winsløws Vej 4, Odense C, Denmark, 5000
Public contact	Lykke Larsen, Department of Infectious Diseases, Odense University Hospital, 45 65412651, llarsen@dadlnet.dk
Scientific contact	Lykke Larsen, Department of Infectious Diseases, Odense University Hospital, 26672029 65412651, llarsen@dadlnet.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	13 December 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

A direct head to head comparison of the specific pneumococcal antibody level pre and post vaccination in the different study groups, for Prenevar 13 and Pneumovax, independently of the immunomodulatory therapy.

Protection of trial subjects:
No measures were done or needed
Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	01 June 2017
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: 139
Worldwide total number of subjects	139
EEA total number of subjects	139

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)	119
From 65 to 84 years	20
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Mulige deltagere udfyldte frivilligt spørgeskema og hvis de ønskede deltagelse i lægemiddelstudie blev de inviteret til samtale

Pre-assignment

Screening details:

lægelig vurdering og spørgeskema

Pre-assignment period milestones

Number of subjects started	139
Intermediate milestone: Number of subjects	vaccinated PCV13: 139
Number of subjects completed	139

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Recipient- Double dosage

Arm description:

recieved 1 ml PCV13 and 1 ml PPV23

Arm type	Experimental
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 ml im

Investigational medicinal product name	23-valent pneumococcal vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 ml im

Arm title	Recipient- Single dosage

Arm description:

recieved 0.5 ml PCV13 + 0.5 ml PPV23

Arm type	Active comparator

Investigational medicinal product name	13-valent pneumococcal conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
1 ml im

Investigational medicinal product name	23-valent pneumococcal vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
1 ml im

Arm title	candidate-double dosage

Arm description:
recieved 1 ml PCV13 and 1 ml PPV23

Arm type	Experimental
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
1 ml im

Investigational medicinal product name	23-valent pneumococcal vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
1 ml im

Arm title	candidate- single dosage

Arm description:
recieved 0,5 ml PCV13 and 0,5 ml PPV23

Arm type	Active comparator
Investigational medicinal product name	13-valent pneumococcal conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
0.5 ml im

Investigational medicinal product name	23-valent pneumococcal vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:
0.5 ml im

Number of subjects in period 1	Recipient- Double dosage	Recipient- Single dosage	candidate-double dosage
Started	35	39	33
Completed	35	37	32
Not completed	0	2	1
Adverse event, serious fatal	-	1	1
Consent withdrawn by subject	-	1	-

Number of subjects in period 1	candidate- single dosage
Started	32
Completed	31
Not completed	1
Adverse event, serious fatal	-
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	139	139	
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)	119	119	
From 65-84 years	20	20	
85 years and over	0	0	
Age continuous Units: years			
median	52		
inter-quartile range (Q1-Q3)	41 to 61	-	
Gender categorical Units: Subjects			
Female	43	43	
Male	96	96	

End points

End points reporting groups	
Reporting group title	Recipient- Double dosage
Reporting group description: recieved 1 ml PCV13 and 1 ml PPV23	
Reporting group title	Recipient- Single dosage
Reporting group description: recieved 0.5 ml PCV13 + 0.5 ml PPV23	
Reporting group title	candidate-double dosage
Reporting group description: recieved 1 ml PCV13 and 1 ml PPV23	
Reporting group title	candidate- single dosage
Reporting group description: recieved 0,5 ml PCV13 and 0,5 ml PPV23	

Primary: protective response	
End point title	protective response
End point description:	
End point type	Primary
End point timeframe: 5 weeks after PPV23	

End point values	Recipient-Double dosage	Recipient-Single dosage	candidate-double dosage	candidate-single dosage
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	39	33	32
Units: 0,1	9	13	20	11

Statistical analyses

Statistical analysis title	protective response
Statistical analysis description: hvor mange har en average pneumococcal AB GMC over 1 mg/L	
Comparison groups	Recipient- Double dosage v Recipient- Single dosage
Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Chi-squared

Statistical analysis title	protective response
Statistical analysis description: forskel i antal peroner med average pneumococcal AB GMC > 1 mg /L	
Comparison groups	candidate-double dosage v candidate- single dosage
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Chi-squared

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 5 weeks after PPV23	
Assessment type	Systematic

Dictionary used	
Dictionary name	none
Dictionary version	1

Reporting groups	
Reporting group title	overall

Reporting group description: -

Serious adverse events	overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	43 / 139 (30.94%)		
number of deaths (all causes)	4		
number of deaths resulting from adverse events	2		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adverse event			
subjects affected / exposed	1 / 139 (0.72%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Adverse event			
subjects affected / exposed	10 / 139 (7.19%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Adverse event			
subjects affected / exposed	2 / 139 (1.44%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	5 / 139 (3.60%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Adverse event			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 139 (2.88%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Adverse event			
subjects affected / exposed	5 / 139 (3.60%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Adverse event			
subjects affected / exposed	1 / 139 (0.72%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Adverse event			
subjects affected / exposed	16 / 139 (11.51%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 2		

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

Non-serious adverse events	overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	62 / 139 (44.60%)		
General disorders and administration site conditions			
Adverse event following immunisation			
subjects affected / exposed	62 / 139 (44.60%)		
occurrences (all)	131		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

We were not able to enroll 200 as planned

Notes: