



Clinical trial results:

Safety and immunogenicity of concomitant administration of the Novavax vaccine and a 20-valent pneumococcal conjugate vaccine in adults aged 60 years: a four-arm, double-blind, non-inferiority trial

Summary

EudraCT number	2022-004118-12
Trial protocol	AT
Global end of trial date	03 June 2024

Results information

Result version number	v1 (current)
This version publication date	11 April 2026
First version publication date	11 April 2026

Trial information

Trial identification

Sponsor protocol code	NVX_PCV20
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Department of Clinical Pharmacology, Medical University of Vienna, +43 14040029810, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Department of Clinical Pharmacology, Medical University of Vienna, +43 14040029810, klin-pharmakologie@meduniwien.ac.at

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	24 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 June 2024
Global end of trial reached?	Yes
Global end of trial date	03 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether the combined administration of NVX XBB.1.5 with a PCV20 is non-inferior to the administration of the NVX vaccine alone in terms of immunogenicity, as determined by anti-RBD antibody levels at day 28.

Protection of trial subjects:

All subjects were under continuous supervision of a physician or an experienced study nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2024
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	Austria: 256
Worldwide total number of subjects	256
EEA total number of subjects	256

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)	126
From 65 to 84 years	130
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study population included female and male subjects aged 60 years or older without clinically relevant comorbidities and concomitant medication that might interfere with the immunogenicity or their eligibility for vaccination.

Pre-assignment

Screening details:

- Males and females
- Able and willing (in the investigator's opinion) to comply with all study requirements.
- Participants, who already received at least two Covid-19 vaccines, of which the last was an mRNA vaccine (BNT162b2 or mRNA-1273) and at least 12 weeks ago
- Only applicable for women: last menstrual bleeding more than one year ago

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

Blinding implementation details:

In this double-blind trial, all participants will receive two injections on Day 1 (one in each shoulder). All participants and physicians, who are responsible for IMP administration and outcome assessment, will be blinded. A separate, unblinded team will independently prepare the syringes for injection. Each syringe will be labeled with the following information: unique participant identifier, unique IMP identifier, and side (left or right).

Arms

Are arms mutually exclusive?	Yes
Arm title	NVX arm

Arm description:

NVX XBB 1.5 plus placebo

Arm type	Experimental
Investigational medicinal product name	Nuvaxovid XBB.1.5
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

administered as single dose, given as intramuscular injections on Day 1

Arm title	PCV20 arm
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Arm description:

PCV20 (Apexxnar®) plus placebo group

Arm type	Active comparator
Investigational medicinal product name	Apexxnar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection

Dosage and administration details:

single dose administration on Day one (in shoulder)

Arm title	Combination arm
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Arm description: NVX XBB.1.5 plus PCV20	
Arm type	Active comparator
Investigational medicinal product name	Nuvaxovid XBB.1.5
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection
Dosage and administration details: administered as single dose, given as intramuscular injections on Day 1	
Investigational medicinal product name	Apexxnar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection
Dosage and administration details: single dose administration on Day one (in shoulder)	
Arm title	Placebo

Arm description: Placebo (normal saline) plus placebo group	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Injection
Dosage and administration details: saline solution, single dose on Day 1	

Number of subjects in period 1	NVX arm	PCV20arm	Combination arm
Started	65	64	64
Completed	65	64	64

Number of subjects in period 1	Placebo
Started	63
Completed	63

Baseline characteristics

Reporting groups

Reporting group title	NVX arm
Reporting group description: NVX XBB 1.5 plus placebo	
Reporting group title	PCV20arm
Reporting group description: PCV20 (Apexxnar®) plus placebo group	
Reporting group title	Combination arm
Reporting group description: NVX XBB.1.5 plus PCV20	
Reporting group title	Placebo
Reporting group description: Placebo (normal saline) plus placebo group	

Reporting group values	NVX arm	PCV20arm	Combination arm
Number of subjects	65	64	64
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)	32	31	31
From 65-84 years	33	33	33
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	34	36	45
Male	31	28	19

Reporting group values	Placebo	Total	
Number of subjects	63	256	
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)	31	125	
From 65-84 years	32	131	

85 years and over	0	0	
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Gender categorical			
Units: Subjects			
Female	36	151	
Male	27	105	

End points

End points reporting groups

Reporting group title	NVX arm
Reporting group description: NVX XBB 1.5 plus placebo	
Reporting group title	PCV20arm
Reporting group description: PCV20 (Apexxnar®) plus placebo group	
Reporting group title	Combination arm
Reporting group description: NVX XBB.1.5 plus PCV20	
Reporting group title	Placebo
Reporting group description: Placebo (normal saline) plus placebo group	

Primary: Omicron-specific anti-spike IgG ELISA units

End point title	Omicron-specific anti-spike IgG ELISA units
End point description: Anti-receptor-binding domain (RBD) antibody levels at Day 28 (BAU/mL)	
End point type	Primary
End point timeframe: 28 Days	

End point values	NVX arm	PCV20arm	Combination arm	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	64	64	63
Units: BAU/ml				
geometric mean (confidence interval 95%)	556 (460 to 672)	309 (242 to 395)	534 (432 to 660)	347 (269 to 449)

Statistical analyses

Statistical analysis title	Statistical analysis
Statistical analysis description: Non-inferiority comparison between 28-day titer values between the combination arm vs the NVX-only arm. Non-inferiority margin: 0.67 for the lower limit of the 95% confidence interval of the geometric mean titer ratio.	
Comparison groups	NVX arm v PCV20arm v Combination arm v Placebo

Number of subjects included in analysis	256
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05 ^[1]
Method	t-test, 2-sided

Notes:

[1] - Primary analysis is based on 95% confidence interval for the non-inferiority analysis.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 0 (Day of vaccination) until day 28 (EoS)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10.0
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Reporting groups

Reporting group title	NVX-CoV2601 plus PCV20
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Reporting group description: -

Reporting group title	NVX-CoV2601 plus Placebo
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Reporting group description: -

Reporting group title	PCV20 plus Placebo
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Reporting group description: -

Reporting group title	Placebo plus Placebo
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Reporting group description: -

Serious adverse events	NVX-CoV2601 plus PCV20	NVX-CoV2601 plus Placebo	PCV20 plus Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 64 (0.00%)	0 / 65 (0.00%)	0 / 64 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Placebo plus Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 63 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	NVX-CoV2601 plus PCV20	NVX-CoV2601 plus Placebo	PCV20 plus Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 64 (84.38%)	41 / 65 (63.08%)	54 / 64 (84.38%)
Immune system disorders			

Systemic immune activation subjects affected / exposed occurrences (all)	Additional description: chills, fever, nausea, vomiting, diarrhea, arthralgia, fatigue, headache		
	54 / 64 (84.38%) 54	33 / 65 (50.77%) 33	26 / 64 (40.63%) 26
Skin and subcutaneous tissue disorders Any local solicited adverse event subjects affected / exposed occurrences (all)	Additional description: Itch, pain, redness, swelling, tenderness, warmth		
	54 / 64 (84.38%) 54	41 / 65 (63.08%) 41	54 / 64 (84.38%) 54

Non-serious adverse events	Placebo plus Placebo		
Total subjects affected by non-serious adverse events subjects affected / exposed	29 / 63 (46.03%)		
Immune system disorders Systemic immune activation subjects affected / exposed occurrences (all)	Additional description: chills, fever, nausea, vomiting, diarrhea, arthralgia, fatigue, headache		
	29 / 63 (46.03%) 29		
Skin and subcutaneous tissue disorders Any local solicited adverse event subjects affected / exposed occurrences (all)	Additional description: Itch, pain, redness, swelling, tenderness, warmth		
	11 / 63 (17.46%) 11		

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/39756693>