Clinical trial results:
CoVacc - Immune response to vaccination against Covid-19, an open multicenter phase IV study

Summary

EudraCT number	2021-000683-30
Trial protocol	SE
Global end of trial date	08 January 2025

Results information

Result version number	v1 (current)
This version publication date	14 May 2025
First version publication date	14 May 2025

Trial information

Trial identification

Sponsor protocol code	CoVacc

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Umeå University
Sponsor organisation address	UNIVERSITETSTORGET 4, Umeå, Sweden,
Public contact	Clas Ahlm, Umeå university, +46 0907850000, clas.ahlm@umu.se
Scientific contact	Clas Ahlm, Umeå university, +46 0907850000, clas.ahlm@umu.se

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	27 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 January 2025
Global end of trial reached?	Yes
Global end of trial date	08 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does antibody development to SARS-CoV-2 S protein differ after vaccination between those who have had a previous SARS-CoV-2 infection compared to Covid-19 naive individuals?

Protection of trial subjects:

The study participants were followed after vaccination for Covid 19. The vaccination was done according to clinical routine and the national coordination so the vaccines used was not a part of the study protocol. All participants were asked about adverse events at study visits 3 months after the vaccine dose was given. All SUSAR were reported accordning to protocol.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 March 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	Sweden: 773
Worldwide total number of subjects	773
EEA total number of subjects	773

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)	603
From 65 to 84 years	138
85 years and over	32

Subject disposition

Recruitment

Recruitment details:

Patients were recruited via national coordinated vaccination units. They were given information and time to read the written information about the study before signing the informed concent. Before given their Covid 19 vaccination the first bloodsamples were collected.

Pre-assignment

Screening details:

798 patients were screened for participation and 773 were enrolled in the study.

Period 1

Period 1 title	Administrive baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not blinded

Arms

Arm title	Administrative group for single arm study

Arm description: -

Arm type	Immune response after covid 19 vaccine
Investigational medicinal product name	Covid 19 vaccin in Sweden
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Injection

Dosage and administration details:

1-2 doses with a couple of weeks apart, according to wich type of vaccin the participant received. Follow up doses were given according to national vaccin programme.
The vaccines were given intramuscular.

Number of subjects in period 1	Administrative group for single arm study
Started	773
Completed	773

Period 2

Period 2 title	Overall trial
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not blinded study

Arms

Arm title	Study arm

Arm description: -

Arm type	Immune response after covid 19 vaccine
Investigational medicinal product name	Covid 19 vaccin in Sweden
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Injection

Dosage and administration details:

1-2 doses with a couple of weeks apart, according to wich type of vaccin the participant received. Follow up doses were given according to national vaccin programme.
The vaccines were given intramuscular.

Number of subjects in period 2	Study arm
Started	773
Completed	547
Not completed	226
Adverse event, non-fatal	9
Patient did not come to study follow up	160
Patients wish	57

Baseline characteristics

Reporting groups	
Reporting group title	Administrive baseline

Reporting group description: -

Reporting group values	Administrive baseline	Total	
Number of subjects	773	773	
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)	603	603	
From 65-84 years	138	138	
85 years and over	32	32	
Gender categorical Units: Subjects			
Female	516	516	
Male	257	257	

End points

End points reporting groups

Reporting group title	Administrative group for single arm study
Reporting group description: -	
Reporting group title	Study arm
Reporting group description: -	

Primary: levels of specific antibodies against the SARS Covid 19 protein

End point title	levels of specific antibodies against the SARS Covid 19 protein
End point description:	
Due to tecnical complications we were forced to create two comparison groups and therefor the total number of trial subject are incorrect (1546). The total number of subjects included in the trial are 773.	
End point type	Primary
End point timeframe:	
From first dose of Covid 19 vaccine and up to 4 years.	

End point values	Administrative group for single arm study	Study arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	773	773		
Units: units				
number (not applicable)	773	773		

Statistical analyses

Statistical analysis title	Descriptive statistics
Statistical analysis description:	
A detailed descriptive analysis will be carried out where deciles of variable of antibody levels are presented, stratified by individuals previously infected/not previously infected infected with SARS-CoV. The primary question will be analyzed with Mann-Whitney U test.	
Comparison groups	Administrative group for single arm study v Study arm
Number of subjects included in analysis	1546
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Confidence interval	
level	Other: 0 %

Notes:

[1] - Each participant is it´s own control.

Secondary: Cellular immune response

End point title	Cellular immune response

End point description:

The percentage of memory B cells specific to SARS-CoV-2 were analyzed in relation to vaccine type
Due to tecnical complications we were forced to create two comparison groups and therefor the total number of trial subject are incorrect (1546). The total number of subjects included in the trial are 773.

End point type	Secondary

End point timeframe:

From the first dose of Covid 19 vaccin and up to 4 years

End point values	Administrative group for single arm study	Study arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	773	773		
Units: units				
number (not applicable)	773	773		

Statistical analyses

Statistical analysis title	Descriptive statistics

Statistical analysis description:

Comparisons within groups for antibody levels in relation to vaccine doses were done by Wilcoxon matched-pairs signed rank test. Comparisons between groups that received different vaccines against Covid-19 were analyzed by Mann-Whitney’s test.

Comparison groups	Administrative group for single arm study v Study arm
Number of subjects included in analysis	1546
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From first Covid 19 dose given and up to 3 months after vaccination.

Adverse event reporting additional description:

This was done after all follow up doses.

Assessment type	Systematic

Dictionary used

Dictionary name	Not specified
Dictionary version	0

Reporting groups

Reporting group title	Overall study particiants

Reporting group description:

If the person has been hospitalized or had another serious event, this will be assessed and in cases where the event can be considered a SUSAR this will be followed up with the help of medical records from the specific situation.
All vaccinations in the study were given according to clinical routine in ordinary care and were not part of the study protocol. Therefor the only adverse events handled by the study was adverse events assessed as SUSARs. All SUSARs were reported to the authorities.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: All vaccinations in the study were given according to clinical routine in ordinary care and were not part of the study protocol. Therefor the only adverse events handled by the study was adverse events assessed as SUSARs. All SUSARs were reported to the authorities

Serious adverse events	Overall study particiants		
Total subjects affected by serious adverse events			
subjects affected / exposed	33 / 773 (4.27%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Testis cancer			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Syncope			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
allergic reaction			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental fatigue			
subjects affected / exposed	2 / 773 (0.26%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	2 / 773 (0.26%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
chest pain			
subjects affected / exposed	2 / 773 (0.26%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Palpitations			

subjects affected / exposed	2 / 773 (0.26%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Broken heart syndrom			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 773 (0.26%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Numbness			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar stroke			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Stroke			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			

Benign paroxysmal positional vertigo				
subjects affected / exposed	1 / 773 (0.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Ileus				
subjects affected / exposed	2 / 773 (0.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	2 / 773 (0.26%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Colitis microscopic				
subjects affected / exposed	1 / 773 (0.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Psoriasis area severity index increased				
subjects affected / exposed	1 / 773 (0.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Tooth infection				
subjects affected / exposed	1 / 773 (0.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Helicobacter infection				
subjects affected / exposed	1 / 773 (0.13%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

subjects affected / exposed	1 / 773 (0.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 773 (0.13%)		
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	Overall study particiants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 773 (0.00%)		

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/34260850

http://www.ncbi.nlm.nih.gov/pubmed/38716734

http://www.ncbi.nlm.nih.gov/pubmed/37575257