



Clinical trial results:

COVERS (COVID-Vaccination Efficiency Risk and Safety Study)

- an open trial for follow-up of efficacy, risk and safety in persons who have been vaccinated against SARS-CoV-2 in Region Skåne with vaccines approved in Sweden

Summary

EudraCT number	2021-000413-17
Trial protocol	SE
Global end of trial date	28 March 2024

Results information

Result version number	v1 (current)
This version publication date	30 January 2026
First version publication date	30 January 2026

Trial information

Trial identification

Sponsor protocol code	COVERS
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Region Skåne
Sponsor organisation address	Getingevägen 4 , Lund , Sweden, 22185
Public contact	Ulf Malmqvist, Region Skåne, ulf.malmqvist@skane.se
Scientific contact	Fredrik Kahn, Lund University, Fredrik.Kahn@med.lu.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	01 October 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 March 2024
Global end of trial reached?	Yes
Global end of trial date	28 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Comparative effect over time on the immune response of approved COVID-19 vaccines used in mass vaccination in Sweden

Protection of trial subjects:

This clinical trial was conducted as a follow-up of effect and safety after mass vaccination of approved vaccines against SARS-Cov-2. The vaccines is not a part of the trial and dose were according to respective manufacturers Summary of Product Characteristics (SPC). Number of vaccinations were determined by the public health authority. Participants reported adverse using a digital app and all SUSARS were reported according to the protocol.

Background therapy:

None

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 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: 3557
Worldwide total number of subjects	3557
EEA total number of subjects	3557

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)	3531

From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was performed in the Scania region (Skåne) in southern Sweden. Participants were non-continuously recruited at four vaccination centres in Scania between April 29, 2021, and February 15, 2022.

Pre-assignment

Screening details:

3558 was screened for participation and one participant were under 18 years old and excluded, 3557 participants were enrolled in the trial.

Period 1

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

Blinding implementation details:

Not applicable

Arms

Arm title	Baseline
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Arm description:

Participants were included in the trial after dose 1, 2 or 3. They were scheduled for follow up and blood samples 3 to 4 weeks after dose 1, and 1, 6, 12 and 24 months after dose 2 and 3.

Arm type	Descriptive
Investigational medicinal product name	Covid 19 vaccin
Investigational medicinal product code	
Other name	Approved vaccines in Sweden against SARS-Cov-2.
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

According to respective manufacturers Summary of Product Characteristics

Number of subjects in period 1	Baseline
Started	3557
Completed	3557

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	3557	3557	
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)	3531	3531	
From 65-84 years	26	26	
85 years and over	0	0	
adults	0	0	
eldery	0	0	
Gender categorical			
Units: Subjects			
Female	2107	2107	
Male	1450	1450	

End points

End points reporting groups

Reporting group title	Baseline
Reporting group description: Participants were included in the trial after dose 1, 2 or 3. They were scheduled for follow up and blood samples 3 to 4 weeks after dose 1, and 1, 6, 12 and 24 months after dose 2 and 3.	

Primary: Change in IgG-antibodies levels to the nucleocapsid (N)-antigen after vaccination with SARS-CoV-2 vaccines.

End point title	Change in IgG-antibodies levels to the nucleocapsid (N)-antigen after vaccination with SARS-CoV-2 vaccines. ^[1]
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End point description:

End point type	Primary
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End point timeframe:

2021/04/29--2024/03/31

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: This is a descriptive study that according to the Swedish MPA is a clinical trial. The study expands on previous research by employing quantitative measurements and mixed-model approaches to provide a more accurate assessment of N-antigen antibody dynamics, including inter-individual variation.

End point values	Baseline			
Subject group type	Reporting group			
Number of subjects analysed	3202			
Units: AU/ml				
log mean (confidence interval 95%)	59 (55 to 64)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

April 29, 2021 to March 31, 2024.

Adverse event reporting additional description:

Participants reported AEs via a questionnaire on an app within 14 days after each vaccination, unsolicited AEs were reported according to the Medical Product Agency's process for adverse reactions. 2651 participants, about 75%, reported AEs via the app. SAE were identified by a regular search of Region Skånes EHR system during the study period.

Assessment type	Systematic
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Dictionary used

Dictionary name	ICD
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Dictionary version	10
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Reporting groups

Reporting group title	All participants
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Reporting group description: -

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	80 / 3557 (2.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm of temporal lobe			
subjects affected / exposed ^[1]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm of long bones of lower limb.			
subjects affected / exposed ^[2]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm of lateral wall of bladder			
subjects affected / exposed ^[3]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm of bladder, unspecified			

subjects affected / exposed ^[4]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Secondary malignant neoplasm of liver and intrahepatic bile duct				
subjects affected / exposed ^[5]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute myeloblastic leukaemia, in remission				
subjects affected / exposed ^[6]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leiomyoma of uterus, unspecified				
subjects affected / exposed ^[7]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm of uncertain behaviour of ureter				
subjects affected / exposed ^[8]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm of uncertain behaviour of bladder				
subjects affected / exposed ^[9]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neoplasm of uncertain behaviour of thyroid gland				
subjects affected / exposed ^[10]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Pulmonary embolism with				

subjects affected / exposed ^[11]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nonrheumatic aortic (valve) stenosis			
subjects affected / exposed ^[12]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Perneoceler			
subjects affected / exposed ^[13]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Legal abortion			
subjects affected / exposed ^[14]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abscess of breast associated with lactation			
subjects affected / exposed ^[15]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Investigations			
subjects affected / exposed ^[16]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Other and unspecific allergy			
subjects affected / exposed ^[17]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Other spontaneous pneumothorax			

subjects affected / exposed ^[18]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Chest pain, unspecified			
subjects affected / exposed ^[19]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Alcohol dependence			
subjects affected / exposed ^[20]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Other bipolar disorder			
subjects affected / exposed ^[21]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder, unspecified.			
subjects affected / exposed ^[22]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Major depressive disorder, single episode, moderate			
subjects affected / exposed ^[23]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Major depressive disorder, single episode, without psychotic features.			
subjects affected / exposed ^[24]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Other depressive episodes			
subjects affected / exposed ^[25]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Major depressive disorder, single			

episode, unspecified				
subjects affected / exposed ^[26]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mixed anxiety and depressive disorder				
subjects affected / exposed ^[27]	3 / 3547 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Acute intoxication sedative and hypnotics				
subjects affected / exposed ^[28]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post-traumatic stress disorder				
subjects affected / exposed ^[29]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asperger's syndrome				
subjects affected / exposed ^[30]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Disorientation, unspecified				
subjects affected / exposed ^[31]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Observation for suspected mental and behavioural disorder				
subjects affected / exposed ^[32]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysphasia and aphasia				
subjects affected / exposed ^[33]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Injury, poisoning and procedural complications			
Fracture of other specified skull and facial bones			
subjects affected / exposed ^[34]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Simple supracondylar fracture without intercondylar fracture of humerus			
subjects affected / exposed ^[35]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Other fracture of lower leg			
subjects affected / exposed ^[36]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foreign body in oesophagus			
subjects affected / exposed ^[37]	2 / 3547 (0.06%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pedal cycle driver injured in noncollision accident in traffic accident			
subjects affected / exposed ^[38]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Driver of other motorcycle injured in unspecific traffic accident			
subjects affected / exposed ^[39]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fall on same level from slipping, tripping, and stumbling without subsequent striking against object			
subjects affected / exposed ^[40]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foreign body entering into or			

through eye or natural orifice.				
subjects affected / exposed ^[41]	2 / 3547 (0.06%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Surgical operation with implant of artificial device as the cause of abnormal reaction.				
subjects affected / exposed ^[42]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute intoxication with sedative or hypnotics				
subjects affected / exposed ^[43]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Exposure to unspecified factor: at unspecific place				
subjects affected / exposed ^[44]	1 / 1 (100.00%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Complications to due to medicine or drugs				
subjects affected / exposed ^[45]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Non-ST elevation (NSTEMI) myocardial infarction				
subjects affected / exposed ^[46]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aortic (valve) stenosis				
subjects affected / exposed ^[47]	1 / 3547 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Paroxysmal atrial fibrillation				

subjects affected / exposed ^[48]	3 / 3547 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Heart failure, unspecified			
subjects affected / exposed ^[49]	2 / 3547 (0.06%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction, type 1			
subjects affected / exposed ^[50]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Multiple sclerosis			
subjects affected / exposed ^[51]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Other specific headache syndromes			
subjects affected / exposed ^[52]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia, unspecified			
subjects affected / exposed ^[53]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia, unspecified			
subjects affected / exposed ^[54]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Unspecified cholesteatoma			
subjects affected / exposed ^[55]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Unspecified hearing loss subjects affected / exposed ^[56] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Gastrointestinal disorders				
Other and unspecified acute appendicitis subjects affected / exposed ^[57] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Ileus, unspecified subjects affected / exposed ^[58] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 2 0 / 0			
Diverticular disease of intestine, part unspecified, without perforation or abscess. subjects affected / exposed ^[59] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Acute pancreatitis, unspecified subjects affected / exposed ^[60] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Pseudocyst of pancreas subjects affected / exposed ^[61] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Melena subjects affected / exposed ^[62] occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 3547 (0.03%) 0 / 1 0 / 0			
Other unspecified abdominal pain				

subjects affected / exposed ^[63]	3 / 3547 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Local infection of the skin and subcutaneous tissue, unspecified			
subjects affected / exposed ^[64]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Generalized skin eruption due to drugs and medicaments taken			
subjects affected / exposed ^[65]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute tubule-interstitial nephrite			
subjects affected / exposed ^[66]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute kidney failure, unspecified			
subjects affected / exposed ^[67]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus of ureter			
subjects affected / exposed ^[68]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Unilateral osteoarthritis resulting from hip dysplasia			
subjects affected / exposed ^[69]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Recurrent dislocation of joint			

subjects affected / exposed ^[70]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbago with sciatica			
subjects affected / exposed ^[71]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacterial infection, unspecified			
subjects affected / exposed ^[72]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Unspecified bacterial pneumonia			
subjects affected / exposed ^[73]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Other specified fever			
subjects affected / exposed ^[74]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infection and inflammatory reaction due to internal joint prosthesis			
subjects affected / exposed ^[75]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Covid 19			
subjects affected / exposed ^[76]	1 / 3547 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[63] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[64] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[65] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[66] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[67] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[68] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[69] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[70] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[71] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[72] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[73] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[74] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[75] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

[76] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The data entry unique patients vs. total events are correct.

Frequency threshold for reporting non-serious adverse events: 0.01 %

Non-serious adverse events	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2552 / 3557 (71.75%)		
Investigations			
Unsolicted AE:s			
subjects affected / exposed	948 / 3557 (26.65%)		
occurrences (all)	1025		
Nervous system disorders			
Postvaccination headache			

subjects affected / exposed	1479 / 3557 (41.58%)		
occurrences (all)	1604		
General disorders and administration site conditions			
Postvaccination fever			
subjects affected / exposed	1112 / 3557 (31.26%)		
occurrences (all)	1167		
Postvaccination chills			
subjects affected / exposed	1004 / 3557 (28.23%)		
occurrences (all)	1042		
Post vaccination shaking chills			
subjects affected / exposed	292 / 3557 (8.21%)		
occurrences (all)	299		
Musculoskeletal and connective tissue disorders			
Postvaccination muscle pain			
subjects affected / exposed	1780 / 3557 (50.04%)		
occurrences (all)	1967		

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/40100206>