Clinical trial results:
Phase 2 multicenter study investigating the tolerability and efficacy of UV1 vaccine in patients with recurrent or metastatic PD-L1 positive (CPS1) head and neck squamous cell carcinoma planned for first-line treatment with pembrolizumab

Summary

EudraCT number	2020-005910-17
Trial protocol	DE
Global end of trial date	26 September 2024

Results information

Result version number	v1 (current)
This version publication date	27 November 2025
First version publication date	27 November 2025

Trial information

Trial identification

Sponsor protocol code	KKSH176

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05075122
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Martin-Luther-University Halle-Wittenberg
Sponsor organisation address	Magdeburger Str. 8, Halle, Germany, 06112
Public contact	Coordinating Investigator, Universitätsklinikum Halle, mascha.binder@usb.de
Scientific contact	Coordinating Investigator, Universitätsklinikum Halle, mascha.binder@usb.de

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	26 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 July 2024
Global end of trial reached?	Yes
Global end of trial date	26 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the clinical performance of the UV1 vaccine as add on to standard pembrolizumab treatment in patients with recurrent or metastatic PD-L1 positive (CPS >=1%) head and neck squamous cell carcinoma in terms of progression free survival according to iRECIST (PFSR@6 months).

Protection of trial subjects:

Treatment of injection site reactions/ allergic reactions was done at investigators discretion. Subject protection was ensured by following high medical and ethical standards consistent with Good Clinical Practice and applicable regulations. The responsible investigator will ensure that this study is conducted in agreement with the Declaration of Helsinki (in its current version) and the laws and regulations. The protocol has been written, and the study was conducted according to the ICH Harmonized Tripartite Guideline for Good Clinical Practice.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 August 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 75
Worldwide total number of subjects	75
EEA total number of subjects	75

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)	37

From 65 to 84 years	33
85 years and over	5

Subject disposition

Recruitment

Recruitment details:

Between August 04, 2021 and July 18, 2023, 75 patients were enrolled at 10 trial sites in Germany. The last patient finished the study treatment in October 17, 2023 and the follow-up period in July 17, 2024.

Pre-assignment

Screening details:

All patients with recurrent or metastatic PD-L1 positive (CPS≥1) head and neck squamous cell carcinoma presenting at the participating trial sites planned for first-line treatment with pembrolizumab were screened for this trial. All patients who met the inclusion/ exclusion criteria were offered participation in this trial.

Period 1

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

Blinding implementation details:

Not applicable

Arms

Are arms mutually exclusive?	Yes
Arm title	A (Calibration Arm)

Arm description:

Patients recived pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.

Arm type	Calibration arm
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200mg flat dose iv every 3 weeks

Arm title	B (Vaccination arm)

Arm description:

Patients received three UV1 vaccinations the week before initiation of pembrolizumab followed by 5 additional UV1 vaccinations every 3 weeks. Patients received pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200mg flat dose iv every 3 weeks

Investigational medicinal product name	UV1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intradermal use

Dosage and administration details:

UV1 vaccination (300 µg UV1 plus 75 µg GM-CSF as adjuvant per vaccination). UV1 vaccination will be applied in a dense schedule with three vaccinations during one week before initiation of pembrolizumab, followed by 5 additional vaccinations every 3 weeks given at the same day as pembrolizumab.

Number of subjects in period 1	A (Calibration Arm)	B (Vaccination arm)
Started	25	50
Completed	25	50

Baseline characteristics

Reporting groups	
Reporting group title	A (Calibration Arm)
Reporting group description:	
Patients recived pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	
Reporting group title	B (Vaccination arm)
Reporting group description:	
Patients received three UV1 vaccinations the week before initiation of pembrolizumab followed by 5 additional UV1 vaccinations every 3 weeks. Patients received pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	

Reporting group values	A (Calibration Arm)	B (Vaccination arm)	Total
Number of subjects	25	50	75
Age categorical			
The trial population included 60 men aund 15 women.			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	64.5	67.5	
standard deviation	± 11.3	± 10.5	-
Gender categorical			
The trial population (75) included 60 men and 15 women.			
Units: Subjects			
female	7	8	15
male	18	42	60
ECOG Performance Status			
Units: Subjects			
ECOG 0	8	17	25
ECOG 1	9	24	33
ECOG 2	7	6	13
ECOG 3	0	1	1
Missing value	1	2	3
Disease status at Recruitment			
Units: Subjects			
Relapse	21	34	55
Initial diagnosis	4	16	20
Tumor stage at the time of recruitment			
Units: Subjects			
T1	3	5	8
T2	3	7	10
T3	3	11	14
T4a	7	17	24
T4b	1	5	6
TX	8	5	13
N stage at recruitment			
Units: Subjects			

N0	5	11	16
T1	2	5	7
T2	10	18	28
T3	6	13	19
TX	2	3	5
M stage at recruitment Units: Subjects			
M0	9	26	35
M1	15	20	35
MX	1	4	5
Disease stage at recruitment Units: Subjects			
Stage I	0	1	1
Stage II	0	5	5
Stage III	1	4	5
Stage IVa	6	12	18
Stage IVb	6	9	15
Stage IVc	12	16	28
N.A.	0	3	3
Time since diagnosis of current disease status Units: Months			
arithmetic mean	3.1	4.8	
standard deviation	± 3.7	± 7.4	-

End points

End points reporting groups

Reporting group title	A (Calibration Arm)
Reporting group description:	
Patients recived pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	
Reporting group title	B (Vaccination arm)
Reporting group description:	
Patients received three UV1 vaccinations the week before initiation of pembrolizumab followed by 5 additional UV1 vaccinations every 3 weeks. Patients received pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	
Subject analysis set title	ITT
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
The database included information on 75 randomized, evaluable patients, 25 in arm A (control, or reference arm) and 50 in arm B (experimental arm with vaccination), forming the ITT full analysis set.	
Subject analysis set title	PP
Subject analysis set type	Per protocol
Subject analysis set description:	
The database included information on 75 randomized, evaluable patients, 25 in arm A (control, or reference arm) and 50 in arm B (experimental arm with vaccination), forming the ITT full analysis set. One patient without receiving a first protocol-defined pembrolizumab cycle was excluded from the per-protocol (PP) population.	
Subject analysis set title	Safety
Subject analysis set type	Safety analysis
Subject analysis set description:	
The safety analysis is based on the total population of 75 patients.	

Primary: Crude proportion of Progression free survival (PFS)

End point title	Crude proportion of Progression free survival (PFS)
End point description:	
PFS is defined as the time from randomization to the date of first observed disease progression (investigator assessment according to iRECIST) or death from any cause. Clinical deterioration in the absence of unequivocal evidence of progression (per iRECIST) is not considered progression for purposes of determining PFS. Subjects who die without a reported prior progression will be considered to have progressed on the date of their death. Subjects who did not progress or die will be censored on the date of their last evaluable tumor assessment. Subjects who did not have any on study tumor assessments and did not die will be censored on the date they were registered. Subjects who started any subsequent anti-cancer therapy without a prior reported progression will be censored at the last evaluable tumor assessment prior to or on the date of initiation of the subsequent anti-cancer therapy.	
End point type	Primary
End point timeframe:	
patients surviving without progression at 6 months after randomisation	

End point values	A (Calibration Arm)	B (Vaccination arm)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	50		
Units: %				
number (confidence interval 90%)				
Crude rate of PFS	40 (24 to 58)	30 (19 to 42)		

Attachments (see zip file)	Progression-free survival from randomisation (ITT)/PFS_ITT.

Statistical analyses

Statistical analysis title	Number of patients surviving free from progression

Statistical analysis description:

With respect to the formal study hypothesis, the two-sided 80% CI (corresponding to the 90% one-sided CI as relevant for superiority) of the rate in the experimental arm does not exclude the 25% boundary, which was pre-defined as futility threshold. Moreover, the 40% finding in the group treated with pembrolizumab alone is higher than expected, possibly suggesting a somewhat favourable patient selection in the FOCUS study. Thus, a positive signal for the experimental treatment cannot be derived.

Comparison groups	A (Calibration Arm) v B (Vaccination arm)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.44
Method	Fisher exact

Primary: Crude PFS rate after 6 months, per-protocol

End point title	Crude PFS rate after 6 months, per-protocol

End point description:

Patient # 01-061 excluded from the ITT analysis due to the lack of any documentation beyond randomisation, is included in a "worst-case" analysis, the crude proportion of patients known to be surviving progression-free at 6 months reduces to 15/51 (29%).

End point type	Primary

End point timeframe:

6 months from randomisation

End point values	A (Calibration Arm)	B (Vaccination arm)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	49		
Units: %				
number (confidence interval 95%)	40 (21 to 61)	31 (18 to 45)		

Statistical analyses

Statistical analysis title	Patients surviving free from progression (PP)
Comparison groups	A (Calibration Arm) v B (Vaccination arm)

Number of subjects included in analysis	74
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.45
Method	Fisher exact

Secondary: Response at end of protocol therapy (ITT)

End point title	Response at end of protocol therapy (ITT)

End point description:

Tumor response according to iRECIST. Only 67 out of 75 patients had a valid restaging result at this time point. The corresponding overall response rate (CR + PR = ORR), is 45% in the control arm (95% CI: 24 … 68%) and 22% in the vaccine arm (95% CI: 11 … 37%) (p = 0.086, Fisher's exact test; descriptive only, due to insufficient power for formal hypothesis test). If the patients without a valid restaging information after protocol therapy are counted as failures (intention-to-treat approach) the corresponding proportions are 10/25 (40%) and 10/50 (20%).

End point type	Secondary

End point timeframe:

Investigated at end of protocol therapy.

End point values	A (Calibration Arm)	B (Vaccination arm)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	22	45	67	
Units: %				
number (not applicable)				
CR	14	4	7	
PR	32	18	22	
SD	5	13	10	
PD unconfirmed	18	27	24	
PD confirmed	32	38	36	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall best response during treatment and follow-up (ITT)

End point title	Overall best response during treatment and follow-up (ITT)

End point description:

The overall best response category achieved during the protocol and the complete follow-up period based on 68 patients with at least one valid iRECIST assessment. Of note, these data may be confounded by non-randomly distributed further antineoplastic treatments during follow-up. The corresponding ORR is 59% in the control arm (95% CI: 36 … 79%) and 33% in the vaccine arm (95% CI: 20 … 48%) (p = 0.064, Fisher's exact test; descriptive only, due to insufficient power for formal hypothesis test), indicating that some additional objective responses were detected after second-line therapy. If the patients without a valid restaging information at all are counted as failures, the corresponding proportions are 13/25 (52%) and 15/50 (30%).

End point type	Secondary

End point timeframe:

During treatment until ed of follow up (2 years max.)

End point values	A (Calibration Arm)	B (Vaccination arm)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	22	46	68	
Units: %				
number (not applicable)				
CR	23	11	15	
PR	36	22	26	
SD	9	20	16	
PD	32	48	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of follow-up (ITT)

End point title	Duration of follow-up (ITT)

End point description:

The average and median documented duration of follow-up since randomisation is slightly shorter than one year, ranging up to 28.7 months, and quite similar in both study arms.

End point type	Secondary

End point timeframe:

Duration of follow-up since randomisation

End point values	A (Calibration Arm)	B (Vaccination arm)	ITT	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	25	50	75	
Units: Months				
arithmetic mean (standard deviation)	11.7 (± 8.4)	11.1 (± 6.2)	11.3 (± 6.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response

End point description:

Subgroup of patients achieving CR or PR

End point type	Secondary

End point timeframe:

Time from randomisation to the detection of progressive disease (or censoring)

End point values	A (Calibration Arm)	B (Vaccination arm)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	15		
Units: Months				
number (not applicable)	6.8	9.5		

Attachments (see zip file)	Duration of Response (ITT)/DoR_ITT.jpg

Statistical analyses

Statistical analysis title	Duration of Response
Comparison groups	A (Calibration Arm) v B (Vaccination arm)
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.69
Method	Logrank

Secondary: Overall Survival

End point title	Overall Survival

End point description:

Based on a total of as yet 46 observed deaths in the ITT population of 75 patients.

End point type	Secondary

End point timeframe:

From the time point of randomisation until death

End point values	A (Calibration Arm)	B (Vaccination arm)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	50		
Units: Months				
median (confidence interval 95%)	13.1 (7.7 to 18.1)	12.6 (9.5 to 19.6)		

Attachments (see zip file)	Overall Survival (ITT)/OSS_ITT.jpg

Statistical analyses

Statistical analysis title	Overall Survival
Comparison groups	A (Calibration Arm) v B (Vaccination arm)
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.53
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	2.32

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Any adverse event occurring between Visit 1 and until 3 months after EOT has to be reported.	
Adverse event reporting additional description:	
All subjects received at least one dose of study treatment were analysed for safety.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups	
Reporting group title	A (Calibration Arm)
Reporting group description:	
Patients recived pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	
Reporting group title	B (Vaccination arm)
Reporting group description:	
Patients received three UV1 vaccinations the week before initiation of pembrolizumab followed by 5 additional UV1 vaccinations every 3 weeks. Patients received pembrolizumab until disease progression (or other discontinuation criteria) and up to a maximum of two years.	

Serious adverse events	A (Calibration Arm)	B (Vaccination arm)	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 25 (40.00%)	28 / 50 (56.00%)	
number of deaths (all causes)	14	32	
number of deaths resulting from adverse events	2	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Laryngeal cancer			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to liver			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Neoplasm progression			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Tumour haemorrhage			
subjects affected / exposed	0 / 25 (0.00%)	2 / 50 (4.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 25 (0.00%)	2 / 50 (4.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal haemorrhage			

subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Gastrostomy failure			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory fume inhalation disorder			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure			

subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral haemorrhage			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorder			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurological decompensation			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 25 (4.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Abdominal pain upper			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer perforation			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis bullous			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin reaction			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Myositis			

subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 25 (4.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Candida infection			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral discitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	1 / 25 (4.00%)	0 / 50 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypercalcaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 25 (4.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 25 (0.00%)	1 / 50 (2.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	A (Calibration Arm)	B (Vaccination arm)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 25 (100.00%)	47 / 50 (94.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	1 / 25 (4.00%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Tumour pain			
subjects affected / exposed	0 / 25 (0.00%)	5 / 50 (10.00%)	
occurrences (all)	0	6	
Vascular disorders			
Lymphoedema			
subjects affected / exposed	2 / 25 (8.00%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	5 / 25 (20.00%)	6 / 50 (12.00%)	
occurrences (all)	5	7	
Injection site erythema			
subjects affected / exposed	0 / 25 (0.00%)	4 / 50 (8.00%)	
occurrences (all)	0	5	
Mucosal inflammation			
subjects affected / exposed	0 / 25 (0.00%)	7 / 50 (14.00%)	
occurrences (all)	0	7	
Oedema			
subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Oedema peripheral			
subjects affected / exposed	0 / 25 (0.00%)	5 / 50 (10.00%)	
occurrences (all)	0	5	
Pain			
subjects affected / exposed	6 / 25 (24.00%)	3 / 50 (6.00%)	
occurrences (all)	6	3	
Pyrexia			

subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 25 (8.00%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Dyspnoea			
subjects affected / exposed	2 / 25 (8.00%)	9 / 50 (18.00%)	
occurrences (all)	2	11	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	4	0	
C-reactive protein increased			
subjects affected / exposed	2 / 25 (8.00%)	4 / 50 (8.00%)	
occurrences (all)	2	4	
Weight decreased			
subjects affected / exposed	3 / 25 (12.00%)	1 / 50 (2.00%)	
occurrences (all)	3	1	
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 25 (4.00%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 25 (4.00%)	5 / 50 (10.00%)	
occurrences (all)	1	5	
Leukopenia			
subjects affected / exposed	2 / 25 (8.00%)	1 / 50 (2.00%)	
occurrences (all)	2	1	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 25 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Ascites			

subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Constipation			
subjects affected / exposed	2 / 25 (8.00%)	2 / 50 (4.00%)	
occurrences (all)	2	2	
Dysphagia			
subjects affected / exposed	3 / 25 (12.00%)	2 / 50 (4.00%)	
occurrences (all)	3	3	
Nausea			
subjects affected / exposed	1 / 25 (4.00%)	4 / 50 (8.00%)	
occurrences (all)	1	4	
Salivary hypersecretion			
subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	1 / 25 (4.00%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	6 / 50 (12.00%)	
occurrences (all)	0	9	
Pruritus			
subjects affected / exposed	1 / 25 (4.00%)	4 / 50 (8.00%)	
occurrences (all)	1	4	
Rash			
subjects affected / exposed	0 / 25 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	2 / 25 (8.00%)	3 / 50 (6.00%)	
occurrences (all)	2	3	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 25 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Back pain			

subjects affected / exposed	1 / 25 (4.00%)	3 / 50 (6.00%)	
occurrences (all)	1	3	
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 25 (4.00%)	3 / 50 (6.00%)	
occurrences (all)	2	3	
Pneumonia			
subjects affected / exposed	3 / 25 (12.00%)	3 / 50 (6.00%)	
occurrences (all)	3	3	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 25 (0.00%)	3 / 50 (6.00%)	
occurrences (all)	0	3	
Hyperkalaemia			
subjects affected / exposed	2 / 25 (8.00%)	4 / 50 (8.00%)	
occurrences (all)	2	6	
Hypocalcaemia			
subjects affected / exposed	2 / 25 (8.00%)	0 / 50 (0.00%)	
occurrences (all)	2	0	
Hypokalaemia			
subjects affected / exposed	3 / 25 (12.00%)	1 / 50 (2.00%)	
occurrences (all)	6	3	
Hyponatraemia			
subjects affected / exposed	4 / 25 (16.00%)	3 / 50 (6.00%)	
occurrences (all)	4	4	

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/38384801