Clinical trial results:
COVID-19 : Immune response in patients with cancer undergoing vaccination against SARS-CoV-2

Summary

EudraCT number	2021-003710-39
Trial protocol	BE PT
Global end of trial date	08 January 2024

Results information

Result version number	v1 (current)
This version publication date	12 July 2025
First version publication date	12 July 2025
Summary attachment (see zip file)	I-SPARC - Final Study Report (I-SPARC_Final_Study_Report.pdf)

Trial information

Trial identification

Sponsor protocol code	IJB-COVID-001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05075538
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Institut Jules Bordet
Sponsor organisation address	Rue Meylemeersch 90,, Anderlecht, Belgium, 1070
Public contact	CTSU, INSTITUT JULES BORDET, cstu.isparc@bordet.be
Scientific contact	Institut Jules Bordet, Dr. Evandro de Azambuja, MD, PhD, evandro.deazambuja@hubruxelles.be

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 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2023
Global end of trial reached?	Yes
Global end of trial date	08 January 2024
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term humoral immune response against SARS-CoV-2 between 3 and 12 months after the last dose (before ICF signature) of an mRNA anti-SARS-CoV-2 vaccine (baseline assessment)

4 cohorts:
- Cohort A.1+ A.2: Subjects with active solid malignancies undergoing immunotherapy, endocrine therapy, or targeted agents (alone or in combination, except if with cytotoxic chemotherapy)
- Cohort A.3: Subjects with active solid malignancies undergoing cytotoxic chemotherapy +/- any other treatment modality in combination
- Cohort B: Subjects with active haematological cancers undergoing systemic treatment
- Cohort C: Subjects with malignancy in complete remission, without active cancer treatment for the last year

Protection of trial subjects:

The protection of subject data and the related rights are guaranteed by the General Data Protection Regulation (European Regulation 2016/679), by the law of 22 August 2002 concerning subject rights in Belgium as well as any new applicable legislation in the participating countries.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 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	Belgium: 152
Worldwide total number of subjects	152
EEA total number of subjects	152

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)	90
From 65 to 84 years	61
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Between 01/12/2023 and 26/10/2023 subjects with histologically or cytologically confirmed cancer diagnosis were recruited in 1 country (Belgium).

Pre-assignment

Screening details:

*Subj undergoing active systemic cancer treatment at the time of the last dose of the anti-SARS-CoV-2 mRNA vaccine in non-metastatic/curative setting or metastatic/palliative setting
*or subj undergoing follow-up after confirmed cancer complete remission without active cancer treatment for the last 12 mo at the time of the last dose of the vaccine

Period 1

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

Arms

Arm title	mRNA vaccination against SARS-CoV-2

Arm description:

anti-SARS-CoV-2 booster dose during the study, as per the national guidelines for vaccination and respecting other local/national recommendations about the ideal timing for vaccination

Arm type	Other
Investigational medicinal product name	Comirnaty/Spikevax
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for injection
Routes of administration	Intramuscular use

Dosage and administration details:

*0.3 mL (single dose after dilution)
*intramuscular (i.m.) administration

Number of subjects in period 1	mRNA vaccination against SARS-CoV-2
Started	152
Completed	77
Not completed	75
Removed by error	1
Consent withdrawn by subject	8
Technical problems	1
Death	4
Study terminated by sponsor	20
Lost to follow-up	6
Not evaluable	3
Protocol deviation	32

Baseline characteristics

Reporting groups	
Reporting group title	mRNA vaccination against SARS-CoV-2
Reporting group description:	
anti-SARS-CoV-2 booster dose during the study, as per the national guidelines for vaccination and respecting other local/national recommendations about the ideal timing for vaccination	

Reporting group values	mRNA vaccination against SARS-CoV-2	Total	
Number of subjects	152	152	
Age categorical			
n (Unites : subjects)			
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)	90	90	
From 65-84 years	61	61	
85 years and over	1	1	
Age continuous			
Units: years			
median	62		
full range (min-max)	24 to 86	-	
Gender categorical			
Units: Subjects			
Female	124	124	
Male	28	28	
Race			
Units: Subjects			
Asian	2	2	
Black or African American	2	2	
Not reported	1	1	
White	147	147	
ECOG Class at Screening			
Units: Subjects			
Zero	78	78	
One	69	69	
Two	3	3	
Missing	2	2	
ECOG class			
Units: Subjects			
Zero - One	147	147	
Two	3	3	
Missing	2	2	

BMI > 25 m^2/kg Units: Subjects			
No	63	63	
Yes	69	69	
Missing	20	20	
Smoking Units: Subjects			
Current	24	24	
Former	26	26	
Never	75	75	
Missing	27	27	
ALC class Units: Subjects			
<1000	32	32	
>=1000	102	102	
Missing	18	18	
Lymphopenia at baseline Units: Subjects			
No	150	150	
Yes	2	2	
Hypogammaglobulinaemia at baseline Units: Subjects			
No	151	151	
Yes	1	1	
Hypertension at inclusion Units: Subjects			
No	100	100	
Yes	52	52	
Hypercholesterolaemia at inclusion Units: Subjects			
No	120	120	
Yes	32	32	
Depression at inclusion Units: Subjects			
No	126	126	
Yes	26	26	
Hypothryoidism at inclusion Units: Subjects			
No	132	132	
Yes	20	20	
N prior vaccin doses Units: Subjects			
Two	25	25	
Three	61	61	
Four	56	56	
Five	10	10	
N months between last vaccination prior inclusion and date inclusion Units: Subjects			
< 6 months	79	79	
6 and 9 months	44	44	

>9 months	29	29	

BMI at screening			
Units: m^2/kg			
median	25.3		
full range (min-max)	16.4 to 53.9	-	
ALC at screening			
Units: µl			
median	1395.0		
full range (min-max)	310 to 6100	-	

Subject analysis sets

Subject analysis set title	EVALUABLE SUBJECTS
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Evaluable subjects: all subjects who received at least two doses of an mRNA anti-SARS-CoV-2 vaccine and from which peripheral blood sample was collected during study

Reporting group values	EVALUABLE SUBJECTS		
Number of subjects	115		
Age categorical			
n (Unites : subjects)			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	70		
From 65-84 years	44		
85 years and over	1		
Age continuous			
Units: years			
median	61		
full range (min-max)	24 to 86		
Gender categorical			
Units: Subjects			
Female	95		
Male	20		
Race			
Units: Subjects			
Asian	2		
Black or African American	2		
Not reported	0		
White	111		
ECOG Class at Screening			
Units: Subjects			

Zero	63		
One	48		
Two	3		
Missing	1		
ECOG class Units: Subjects			
Zero - One	111		
Two	3		
Missing	1		
BMI > 25 m^2/kg Units: Subjects			
No	45		
Yes	53		
Missing	17		
Smoking Units: Subjects			
Current	16		
Former	19		
Never	62		
Missing	18		
ALC class Units: Subjects			
<1000	24		
>=1000	76		
Missing	15		
Lymphopenia at baseline Units: Subjects			
No	114		
Yes	1		
Hypogammaglobulinaemia at baseline Units: Subjects			
No	114		
Yes	1		
Hypertension at inclusion Units: Subjects			
No	82		
Yes	33		
Hypercholesterolaemia at inclusion Units: Subjects			
No	93		
Yes	22		
Depression at inclusion Units: Subjects			
No	92		
Yes	23		
Hypothryoidism at inclusion Units: Subjects			
No	105		
Yes	10		
N prior vaccin doses Units: Subjects			

Two	24		
Three	44		
Four	38		
Five	9		
N months between last vaccination prior inclusion and date inclusion Units: Subjects			
< 6 months	42		
6 and 9 months	44		
>9 months	29		
BMI at screening Units: m^2/kg			
median	25.3		
full range (min-max)	16.9 to 53.9		
ALC at screening Units: µl			
median	1395.0		
full range (min-max)	440 to 6100		

End points

End points reporting groups

Reporting group title	mRNA vaccination against SARS-CoV-2

Reporting group description:

anti-SARS-CoV-2 booster dose during the study, as per the national guidelines for vaccination and respecting other local/national recommendations about the ideal timing for vaccination

Subject analysis set title	EVALUABLE SUBJECTS
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Evaluable subjects: all subjects who received at least two doses of an mRNA anti-SARS-CoV-2 vaccine and from which peripheral blood sample was collected during study

Primary: Long-term response rate

End point title	Long-term response rate[1]

End point description:

The proportion of subjects that have detectable titers of specific antibody against SARS-CoV-2 spike protein, measured by Elecsys® Anti-SARS-CoV-2 S, between 3 and 12 months after the last dose (before ICF signature) of an mRNA anti-SARS-CoV-2 vaccine.

107 evaluable subjects at baseline
*) 56 cohort A1+A2
*) 17 cohort A3
*) 9 cohort B
*) 25 cohort C

The immune response rate was 100% in all subjects, in each cohort, at baseline.
• Cohort A1+A2: 56/56 = 100% (95% CI, 94% to 100%).
• Cohort A3: 17/17 = 100% (95% CI, 80% to 100%)
• Cohort B: 9/9 = 100% (95% CI, 66% to 100%)
• Cohort C: 25/25 = 100% (95% CI, 86% to 100%)

End point type	Primary

End point timeframe:

Baseline

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: Not applicable: single-arm study. The aim was to estimate the immune response rate within each cohort.

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	107[2]			
Units: Subjects				
Immune response	107			
No immune response	0			

Notes:

[2] - Of the 115 subjects, 107 were evaluable at baseline (8 not evaluable)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of immune response

End point title	Duration of immune response

End point description:

The proportion of subjects that have detectable titers of specific antibody against SARS-CoV-2 spike protein, measured by Elecsys® Anti-SARS-CoV-2 S, at the final study assessment timepoint, namely at 6 months (+/- 4 weeks) after the baseline assessment or at 6 months (+ 4 weeks/- 8 weeks) after the first booster dose after ICF signature, if a booster dose of the vaccine is administered during the study per local / national health policy guidelines.
Duration of immune response cannot be determined, as no subject had a non-response during study.

End point type	Secondary

End point timeframe:

Final assessment

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	115			
Units: months				
median (inter-quartile range (Q1-Q3))				
NA	9999 (9999 to 9999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Immune response by cohort

End point title	Immune response by cohort

End point description:

The proportion of subjects that have detectable titers of specific antibody against SARS-CoV-2 spike protein, measured by Elecsys® Anti-SARS-CoV-2 S, by cohort (specified in section 3.):
i) between 3 and 12 months after the last dose before ICF signature; and
ii) at the final study assessment timepoint, namely at 6 months (+/- 4 weeks) after baseline assessment or 6 months (+ 4 weeks/- 8 weeks) after the first booster dose after ICF signature, if a booster dose is administered during the study per local / national health policy guidelines.

Of the 115 evaluable subjects:
*) 107 evaluable at baseline
*) 52 evaluable at post-boost
*) 56 evaluable at final assessment

Immune response 100% in each cohort at each time

	cohort			
	A1+A2	A3	B	C
baseline	56/56	17/17	9/9	25/25
post-boost	25/25	12/12	6/6	9/9
final	30/30	8/8	4/4	14/14

End point type	Secondary

End point timeframe:

Baseline, Post-boost and Final Assessment

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	115			
Units: Subjects				
Immune response rate	115			

Statistical analyses

No statistical analyses for this end point

Post-hoc: Absolute Titers of Anti-Spike Antibodies at baseline

End point title	Absolute Titers of Anti-Spike Antibodies at baseline

End point description:

At baseline, the overall median anti-Spike antibody titer was 9,017 U/mL [IQR, 2,180–26,871], with a significant difference observed across cohorts (p=0.005). Patients in cohort A.3 exhibited lower titers (3,875 U/mL [IQR, 202–13,863]) compared to those in cohort A.1–2 (11,293 U/mL [IQR, 3,359–26,487], p=0.003) and in cohort C (8,828 U/mL [IQR, 3,785–28,582], p=0.07). Patients in cohort B had the lowest titers (330 U/mL [IQR, 107–2,888]), which were significantly lower than those in cohort A.1–2 (p=0.004) and cohort C (p=0.02).

End point type	Post-hoc

End point timeframe:

baseline

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	107[3]			
Units: U/mL				
median (inter-quartile range (Q1-Q3))	9.017 (2.180 to 26.871)			

Notes:

[3] - N=107 evaluable at baseline

Statistical analyses

No statistical analyses for this end point

Post-hoc: Absolute Titers of Anti-Spike Antibodies at post-boost

End point title	Absolute Titers of Anti-Spike Antibodies at post-boost

End point description:

At post-booster timepoint, the overall median anti-Spike antibody increased to 30,079 U/mL [IQR, 13,669–56,337], with significant differences across cohorts (p=0.012). Patients in cohort B again

exhibited the lowest titers (1,504 U/mL [IQR, 287–21,182]), which were significantly lower than those in cohort A.1–2 (35,239 U/mL [IQR, 23,192–64,098], p=0.005) and in cohort C (30,414 U/mL [IQR, 9,722–39,142], p=0.03). While patients in cohort A.3 had numerically lower titers (25,094 U/mL [IQR, 3,666–62,819]) than cohort A.1–2 and cohort C, these differences were not statistically significant (p=0.18 and p=0.55, respectively)

End point type	Post-hoc

End point timeframe:

post-boost

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	52[4]			
Units: U/mL				
median (inter-quartile range (Q1-Q3))	30.079 (13.669 to 56.337)			

Notes:

[4] - 52 evaluable subjects at post-boost

Statistical analyses

No statistical analyses for this end point

Post-hoc: Absolute Titers of Anti-Spike Antibodies at final study assessment

End point title	Absolute Titers of Anti-Spike Antibodies at final study assessment

End point description:

At the final study assessment, the overall median anti-Spike antibody titer was 10,024 U/mL [IQR, 5,040–25,814], with no statistically significant difference across cohorts (p=0.053). Median titers remained numerically lower in patients in cohort A.3 (7,720 U/mL [IQR, 2,334–14,041]) and cohort B (3,941 U/mL [IQR, 1,193–6,433]) compared to those in cohort A.1–2 (10,106 U/mL [IQR, 5,302–24,628]) and in cohort C (13,659 U/mL [IQR, 8,792–31,475])

End point type	Post-hoc

End point timeframe:

final study assessment

End point values	EVALUABLE SUBJECTS			
Subject group type	Subject analysis set			
Number of subjects analysed	56[5]			
Units: U/mL				
median (inter-quartile range (Q1-Q3))	10.024 (5.040 to 25.814)			

Notes:

[5] - 56 evaluable at final study assessment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Overall trial	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25

Frequency threshold for reporting non-serious adverse events: 1 %

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: No adverse events have been reported in the 152 included subjects.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 January 2022	New amended other study documents New amended patient information sheet/informed consent (including addendum) New amended protocol
14 April 2022	New amended patient information sheet/informed consent (including addendum) New amended protocol
02 May 2022	New amended patient information sheet/informed consent (including addendum) New amended protocol
30 June 2022	Addition of at least a new site or a site whose LEC did not reply initially or moved site
06 October 2022	New amended patient information sheet/informed consent (including addendum) New amended protocol New amended documents or information related to IMP or IMPD
02 February 2023	New amended patient information sheet/informed consent (including addendum) New amended protocol New amended Reference Safety Information New amended documents or information related to IMP or IMPD
16 November 2023	New amended patient information sheet/informed consent (including addendum) New amended protocol New amended Reference Safety Information New amended documents or information related to IMP or IMPD

Notes:

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.

The trial has been stopped prematurely due to slow accrual. All subjects had an immune response, resulting in a total immune response rate in all cohorts. Assessing differences in immune response according to subjects’characteristics was not possible

Notes: