Clinical trial results:
The impact of BNT162b2 mRNA vaccine on adaptive and innate immune responses

Summary

EudraCT number	2021-000182-33
Trial protocol	NL
Global end of trial date	21 January 2022

Results information

Result version number	v1 (current)
This version publication date	21 January 2023
First version publication date	21 January 2023

Trial information

Trial identification

Sponsor protocol code	76421

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Radboudumc
Sponsor organisation address	Geert Grooteplein Zuid 10, Nijmegen, Netherlands,
Public contact	Konstantin Föhse, Radboudumc, konstantin.fohse@radboudumc.nl
Scientific contact	Konstantin Föhse, Radboudumc, konstantin.fohse@radboudumc.nl

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	05 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 January 2022
Global end of trial reached?	Yes
Global end of trial date	21 January 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to analyze the effects of BNT162b2 vaccination on both the specific adaptive immune responses and the responsiveness of human immune cells upon stimulation with heterologous pathogens.

Protection of trial subjects:

Data from trial subjects was pseudonymized.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 January 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	Netherlands: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	16
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Healthcare workers from the Radboud University Medical Center, Nijmegen were enrolled who received the BNT162b2 mRNA COVID-19 vaccine as per national vaccination campaign and provided informed consent. Key exclusion criteria included a medical history of COVID-19.

Period 1

Period 1 title	T3
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All participants

Arm description:

According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Injection

Dosage and administration details:

30 µg

Number of subjects in period 1	All participants
Started	16
Completed	13
Not completed	3
Dropped out because they had COVID-19 during study	3

Period 2

Period 2 title	T4
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All participants

Arm description:

According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Injection

Dosage and administration details:

30 µg

Number of subjects in period 2	All participants
Started	13
Completed	13

Period 3

Period 3 title	T5
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	All participants

Arm description:

According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign

Arm type	Experimental
Investigational medicinal product name	BNT162b2
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Injection

Dosage and administration details:

30 µg

Number of subjects in period 3	All participants
Started	13
Completed	13

Baseline characteristics

End points

End points reporting groups

Reporting group title	All participants
Reporting group description:	
According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign	
Reporting group title	All participants
Reporting group description:	
According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign	
Reporting group title	All participants
Reporting group description:	
According to inclusion criterion: subjects who were vaccinated with BNT162b2 as per national vaccination campaign	

Primary: Neutralizing capacity of the serum against the D614G strain

End point title	Neutralizing capacity of the serum against the D614G strain
End point description:	
End point type	Primary
End point timeframe:	
T2 (Two weeks after the second dose) T3 (Six months after the first dose) T4 (Four weeks after the booster vaccination, which was approximately one year after the first dose).	

End point values	All participants	All participants	All participants	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13[1]	13	13	
Units: IU/ml	454	89	1533	

Notes:

[1] - 3 drop-outs because they had COVID-19 during study period

Statistical analyses

Statistical analysis title	Comparing geometric mean titers
Comparison groups	All participants v All participants v All participants
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: Full study period	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.1

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

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 were reported by the subjects. Common side effects of vaccination or blood collection were not regarded as adverse events, as pre-defined in the protocol.

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