



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