



Clinical trial results:

A multi-site, Phase I/II, 2-part, dose escalation trial investigating the safety and immunogenicity of a prophylactic SARS-CoV-2 RNA vaccine (BNT162b3) against COVID-19 using different dosing regimens in healthy adults

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2020-003267-26 |
| Trial protocol | DE |
| Global end of trial date | 07 February 2022 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 22 February 2023 |
| First version publication date | 22 February 2023 |

Trial information

Trial identification

| | |
|-----------------------|-----------|
| Sponsor protocol code | BNT162-04 |
|-----------------------|-----------|

Additional study identifiers

| | |
|------------------------------------|-----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04537949 |
| WHO universal trial number (UTN) | U1111-1254-4840 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | BioNTech SE |
| Sponsor organisation address | An der Goldgrube 12, Mainz, Germany, 55131 |
| Public contact | BioNTech clinical trials patient information, BioNTech SE, 0049 6131 90840, patients@biontech.de |
| Scientific contact | BioNTech clinical trials patient information, BioNTech SE, 0049 6131 90840, patients@biontech.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 | 22 July 2022 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 February 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To describe the safety and tolerability profiles of a prophylactic BNT162b3 in healthy adults after prime/boost (P/B) immunization.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 09 September 2020 |
| 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 | Germany: 96 |
| Worldwide total number of subjects | 96 |
| EEA total number of subjects | 96 |

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) | 70 |
| From 65 to 84 years | 26 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Participants were selected from the volunteer panel at the clinical CRO, who responded to either generic or study-specific advertisements in social media, or who contacted the clinical CRO via a web-based study participant recruitment portal. Participants were selected from this pool of volunteers according to inclusion and exclusion criteria.

Pre-assignment

Screening details:

All enrolled participants were allocated to treatment.

Period 1

| | |
|------------------------------|-----------------|
| Period 1 title | Treatment Phase |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|--|
| Arm title | Part A Participants Aged 18 to 55 Years - 3 µg |
|------------------|--|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 18 to 55 Years - 10 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 18 to 55 Years - 20 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|---|
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 18 to 55 Years - 30 µg |
| Arm description: | |
| BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee). | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 56 to 85 Years - 3 µg |
| Arm description: | |
| BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 56 to 85 Years - 10 µg |
| Arm description: | |
| BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 56 to 85 Years - 20 µg |
| Arm description: | |
| BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |

| | |
|--|-------------------|
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 56 to 85 Years - 30 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| Number of subjects in period 1 | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg |
|---|--|---|---|
| Started | 12 | 12 | 12 |
| Completed | 11 | 12 | 12 |
| Not completed | 1 | 0 | 0 |
| Personal reasons not related to the IMP | 1 | - | - |

| Number of subjects in period 1 | Part A Participants Aged 18 to 55 Years - 30 µg | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg |
|---|---|--|---|
| Started | 12 | 12 | 12 |
| Completed | 12 | 12 | 12 |
| Not completed | 0 | 0 | 0 |
| Personal reasons not related to the IMP | - | - | - |

| Number of subjects in period 1 | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|---|
| Started | 12 | 12 |
| Completed | 12 | 12 |
| Not completed | 0 | 0 |
| Personal reasons not related to the IMP | - | - |

| Period 2 | |
|--|---|
| Period 2 title | Follow-up Phase |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |
| Arms | |
| Are arms mutually exclusive? | Yes |
| Arm title | Part A Participants Aged 18 to 55 Years - 3 µg |
| Arm description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 18 to 55 Years - 10 µg |
| Arm description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 18 to 55 Years - 20 µg |
| Arm description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL. | |
| Arm title | Part A Participants Aged 18 to 55 Years - 30 µg |

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|--|
| Arm title | Part A Participants Aged 56 to 85 Years - 3 µg |
|------------------|--|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 56 to 85 Years - 10 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 56 to 85 Years - 20 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| | |
|------------------|---|
| Arm title | Part A Participants Aged 56 to 85 Years - 30 µg |
|------------------|---|

Arm description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b3 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Two injections administered intramuscularly (upper arm, musculus deltoideus) approximately 21 days apart. Injection volumes were up to 1.5 mL.

| Number of subjects in period 2 | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg |
|---------------------------------------|--|---|---|
| Started | 11 | 12 | 12 |
| Completed | 8 | 8 | 12 |
| Not completed | 3 | 4 | 0 |
| Personal reasons | - | - | - |
| Consent withdrawn by subject | - | - | - |
| Roll-over into trial BNT162-14 | 3 | 1 | - |
| Lost to follow-up | - | 3 | - |

| Number of subjects in period 2 | Part A Participants Aged 18 to 55 Years - 30 µg | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg |
|---------------------------------------|---|--|---|
| Started | 12 | 12 | 12 |
| Completed | 9 | 9 | 11 |
| Not completed | 3 | 3 | 1 |
| Personal reasons | 1 | 1 | - |
| Consent withdrawn by subject | - | 1 | - |
| Roll-over into trial BNT162-14 | 2 | 1 | 1 |
| Lost to follow-up | - | - | - |

| Number of subjects in period 2 | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---------------------------------------|---|---|
| Started | 12 | 12 |
| Completed | 7 | 6 |
| Not completed | 5 | 6 |
| Personal reasons | - | - |
| Consent withdrawn by subject | - | - |
| Roll-over into trial BNT162-14 | 5 | 6 |
| Lost to follow-up | - | - |

Baseline characteristics

Reporting groups

| | |
|--|---|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 3 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 10 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 20 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 30 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee). | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 3 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 10 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 20 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 30 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |

| Reporting group values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg |
|---------------------------------------|--|---|---|
| Number of subjects | 12 | 12 | 12 |
| Age categorical Units: Subjects | | | |
| Age continuous Units: years | | | |
| arithmetic mean | 39.32 | 31.20 | 31.89 |
| standard deviation | ± 9.79 | ± 9.11 | ± 13.51 |
| Gender categorical Units: Subjects | | | |
| Female | 3 | 4 | 7 |
| Male | 9 | 8 | 5 |

| | | | |
|---|---------|---------|---------|
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 12 | 12 | 12 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 12 | 12 | 11 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Weight | | | |
| Units: kg | | | |
| arithmetic mean | 72.74 | 71.68 | 71.40 |
| standard deviation | ± 11.43 | ± 11.67 | ± 14.40 |
| Body mass index | | | |
| Units: kg/m ² | | | |
| arithmetic mean | 23.89 | 24.23 | 23.80 |
| standard deviation | ± 2.92 | ± 3.68 | ± 2.74 |

| | | | |
|-------------------------------|---|--|---|
| Reporting group values | Part A Participants Aged 18 to 55 Years - 30 µg | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg |
| Number of subjects | 12 | 12 | 12 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|--------|--------|--------|
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 37.28 | 66.08 | 69.32 |
| standard deviation | ± 6.40 | ± 7.16 | ± 8.74 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 8 | 9 | 8 |
| Male | 4 | 3 | 4 |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 12 | 12 | 12 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 12 | 12 | 12 |
| More than one race | 0 | 0 | 0 |

| | | | |
|-------------------------|---|---|---|
| Unknown or Not Reported | 0 | 0 | 0 |
|-------------------------|---|---|---|

| | | | |
|--|------------------|------------------|------------------|
| Weight Units: kg arithmetic mean standard deviation | 71.20 ± 13.80 | 76.05 ± 11.88 | 70.90 ± 10.69 |
| Body mass index Units: kg/m ² arithmetic mean standard deviation | 23.69 ± 2.03 | 25.92 ± 1.66 | 24.69 ± 3.09 |

| Reporting group values | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg | Total |
|------------------------------------|---|---|-------|
| Number of subjects | 12 | 12 | 96 |
| Age categorical Units: Subjects | | | |

| | | | |
|--|------------------|------------------|----|
| Age continuous Units: years arithmetic mean standard deviation | 64.93 ± 6.63 | 66.42 ± 6.82 | - |
| Gender categorical Units: Subjects | | | |
| Female | 9 | 6 | 54 |
| Male | 3 | 6 | 42 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 12 | 12 | 96 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 12 | 12 | 95 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Weight Units: kg arithmetic mean standard deviation | 69.06 ± 14.25 | 84.43 ± 17.53 | - |
| Body mass index Units: kg/m ² arithmetic mean standard deviation | 24.03 ± 3.17 | 26.73 ± 2.75 | - |

End points

End points reporting groups

| | |
|--|---|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 3 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 10 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 20 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 18 to 55 Years - 30 µg |
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| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
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| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 20 µg |
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| | |
|---|---|
| Reporting group title | Part A Participants Aged 56 to 85 Years - 10 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 20 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |
| Reporting group title | Part A Participants Aged 56 to 85 Years - 30 µg |
| Reporting group description: BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen) | |

Primary: Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose

| | |
|-----------------|--|
| End point title | Number of Participants With Solicited Local Reactions at the Injection Site (Pain, Tenderness, Erythema/Redness, Induration/Swelling) Recorded up to 7 Days After Each IMP Dose ^[1] |
|-----------------|--|

End point description:

Solicited local reactions at the injection site (pain, tenderness, erythema/redness, and induration/swelling) were monitored and graded using criteria based on the guidance given in US FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials". The reporting of local reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. 9999 indicates data not available as the boost immunization was withheld for 30 µg younger cohort following Safety Review Committee decision.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 8 for Prime Immunization and from Day 22 to Day 29 for Boost Immunization

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: No statistical analyses were planned for this primary end point.

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|--|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| Prime up to Day 7: any local reaction | 9 | 9 | 12 | 12 |
| Prime up to Day 7: any grade ≥3 local reaction | 0 | 0 | 2 | 2 |
| Boost up to Day 7: any local reaction | 9 | 9 | 12 | 9999 |
| Boost up to Day 7: any grade ≥3 local reaction | 0 | 0 | 1 | 9999 |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|------------------|--|---|---|---|
| | | | | |

| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
|--|-----------------|-----------------|-----------------|-----------------|
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| Prime up to Day 7: any local reaction | 4 | 10 | 10 | 9 |
| Prime up to Day 7: any grade ≥ 3 local reaction | 0 | 0 | 0 | 0 |
| Boost up to Day 7: any local reaction | 2 | 9 | 8 | 11 |
| Boost up to Day 7: any grade ≥ 3 local reaction | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose

| | |
|-----------------|--|
| End point title | Number of Participants With Solicited Systemic Reactions (Nausea, Vomiting, Diarrhea, Headache, Fatigue, Myalgia, Arthralgia, Chills, Loss of Appetite, Malaise, and Fever) Recorded up to 7 Days After Each IMP Dose ^[2] |
|-----------------|--|

End point description:

Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) were monitored and graded using criteria based on the guidance given in US FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials". The reporting of systemic reactions was based on the participant's assessments via daily solicited reports in the participant diaries. Safety Set - all participants who received at least one dose of the IMP. 9999 indicates data not available as the boost immunization was withheld for 30 μ g younger cohort following Safety Review Committee decision.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Day 1 to Day 8 for Prime Immunization and from Day 22 to Day 29 for Boost Immunization

Notes:

[2] - 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: No statistical analyses were planned for this primary end point.

| End point values | Part A Participants Aged 18 to 55 Years - 3 μ g | Part A Participants Aged 18 to 55 Years - 10 μ g | Part A Participants Aged 18 to 55 Years - 20 μ g | Part A Participants Aged 18 to 55 Years - 30 μ g |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| Prime up to Day 7: any systemic reaction | 4 | 10 | 12 | 12 |
| Prime up to Day 7: any grade ≥ 3 systemic reaction | 0 | 0 | 1 | 3 |
| Boost up to Day 7: any systemic reaction | 10 | 9 | 12 | 9999 |
| Boost up to Day 7: any grade ≥ 3 systemic reaction | 0 | 2 | 4 | 9999 |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| Prime up to Day 7: any systemic reaction | 3 | 9 | 9 | 10 |
| Prime up to Day 7: any grade ≥3 systemic reaction | 0 | 3 | 0 | 2 |
| Boost up to Day 7: any systemic reaction | 2 | 10 | 9 | 12 |
| Boost up to Day 7: any grade ≥3 systemic reaction | 0 | 2 | 2 | 2 |

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Prime Immunization up to Boost Immunization or 28 Days After Prime Immunization

| | |
|-----------------|---|
| End point title | The Percentage of Participants With at Least 1 Unsolicited Treatment Emergent Adverse Event (TEAE) Occurring After Prime Immunization up to Boost Immunization or 28 Days After Prime Immunization ^[3] |
|-----------------|---|

End point description:

Treatment emergent adverse events (TEAEs) were analyzed by age group, dose level, and for each IMP dose. The number and percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

28 days following first IMP dose or up to second IMP dose (whichever was first)

Notes:

[3] - 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: No statistical analyses were planned for this primary end point.

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAE | 42 | 25 | 25 | 50 |
| Any grade ≥3 TEAE | 0 | 0 | 0 | 0 |

| End point values | Part A | Part A | Part A | Part A |
|-------------------------|--------|--------|--------|--------|
|-------------------------|--------|--------|--------|--------|

| | Participants Aged 56 to 85 Years - 3 µg | Participants Aged 56 to 85 Years - 10 µg | Participants Aged 56 to 85 Years - 20 µg | Participants Aged 56 to 85 Years - 30 µg |
|-----------------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAE | 17 | 17 | 25 | 42 |
| Any grade ≥3 TEAE | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Primary: The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring up to 28 Days After Boost Immunization or After Prime Immunization (if no Boost Immunization)

| | |
|-----------------|--|
| End point title | The Percentage of Participants With at Least 1 Unsolicited TEAE Occurring up to 28 Days After Boost Immunization or After Prime Immunization (if no Boost Immunization) ^[4] |
|-----------------|--|

End point description:

Treatment emergent adverse events (TEAEs) were analyzed by age group, dose level, and for each IMP dose. The percentage of participants reporting at least one TEAE was summarized by adverse event types (any TEAE and any grade ≥3 TEAE) using the Safety Set. Safety Set - all participants who received at least one dose of the IMP.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

28 days following second IMP dose or first IMP dose (if no second IMP dose as given)

Notes:

[4] - 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: No statistical analyses were planned for this primary end point.

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|-----------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAE | 50 | 33 | 42 | 50 |
| Any grade ≥3 TEAE | 0 | 0 | 0 | 0 |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|-----------------------------------|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Percentage of participants | | | | |

| | | | | |
|-------------------------|----|----|----|----|
| number (not applicable) | | | | |
| Any TEAE | 58 | 25 | 42 | 50 |
| Any grade ≥ 3 TEAE | 0 | 0 | 0 | 8 |

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses

| | |
|---|-------------------------------|
| End point title | Functional Antibody Responses |
| End point description: | |
| At 7 and 21 days after primary immunization and at 7, 14, 21, 28 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 μ g younger cohort following Safety Review Committee decision. 9999 indicates missing Day 36 data of 10 μ g and 20 μ g younger cohort as they have only re-consented to Clinical Trial Protocol 7.0 (introducing visit 5a/Day 36) on/after their Day 43. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 50 days following first IMP dose | |

| End point values | Part A Participants Aged 18 to 55 Years - 3 μ g | Part A Participants Aged 18 to 55 Years - 10 μ g | Part A Participants Aged 18 to 55 Years - 20 μ g | Part A Participants Aged 18 to 55 Years - 30 μ g |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 7 days after Prime Immunization (Day 8) | 5.0 (5.0 to 5.0) | 5.1 (4.8 to 5.5) | 5.0 (5.0 to 5.0) | 5.0 (5.0 to 5.0) |
| 21 days after Prime Immunization (Day 22) | 6.1 (4.5 to 8.4) | 25.9 (13.8 to 48.7) | 8.9 (6.0 to 13.3) | 12.2 (7.5 to 20.0) |
| 7 days after Boost Immunization (Day 29) | 51.5 (26.4 to 100.3) | 479.5 (300.3 to 765.5) | 106.8 (58.2 to 196.0) | 10.0 (6.5 to 15.4) |
| 14 days after Boost Immunization (Day 36) | 60.6 (33.5 to 109.8) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 10.3 (6.9 to 15.4) |
| 21 days after Boost Immunization (Day 43) | 36.4 (20.0 to 66.2) | 116.5 (79.6 to 170.4) | 201.6 (104.9 to 387.2) | 9.7 (5.7 to 16.5) |
| 28 days after Boost Immunization (Day 50) | 31.7 (18.5 to 54.6) | 80.0 (49.1 to 130.4) | 219.8 (117.5 to 411.1) | 7.9 (5.0 to 12.5) |

| End point values | Part A Participants Aged 56 to 85 Years - 3 μ g | Part A Participants Aged 56 to 85 Years - 10 μ g | Part A Participants Aged 56 to 85 Years - 20 μ g | Part A Participants Aged 56 to 85 Years - 30 μ g |
|-----------------------------|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |

| | | | | |
|---|----------------------|------------------------|------------------------|------------------------|
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 7 days after Prime Immunization (Day 8) | 5.0 (5.0 to 5.0) | 5.0 (5.0 to 5.0) | 7.3 (3.2 to 16.6) | 5.0 (5.0 to 5.0) |
| 21 days after Prime Immunization (Day 22) | 6.3 (4.8 to 8.3) | 5.3 (4.9 to 5.8) | 15.0 (5.9 to 37.9) | 9.4 (5.4 to 16.4) |
| 7 days after Boost Immunization (Day 29) | 53.4 (25.1 to 113.7) | 51.9 (25.0 to 107.4) | 320.0 (189.7 to 539.7) | 207.5 (118.0 to 364.8) |
| 14 days after Boost Immunization (Day 36) | 77.7 (40.4 to 149.4) | 219.8 (148.5 to 325.4) | 320.0 (169.3 to 604.9) | 359.2 (204.0 to 632.6) |
| 21 days after Boost Immunization (Day 43) | 53.4 (27.5 to 103.6) | 155.4 (105.0 to 230.1) | 285.1 (152.6 to 532.7) | 261.4 (136.0 to 502.6) |
| 28 days after Boost Immunization (Day 50) | 41.2 (20.5 to 82.8) | 138.5 (87.9 to 218.2) | 232.9 (131.1 to 413.8) | 195.8 (109.4 to 350.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers

| | |
|------------------------|--|
| End point title | Fold Increase in Functional Antibody Titers |
| End point description: | At 7 and 21 days after primary immunization and at 7, 14, 21, and 28 days after the boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. |
| End point type | Secondary |
| End point timeframe: | Up to 50 days following first IMP dose |

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|---|--|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 7 days after Prime Immunization (Day 8) | 1.0 (1.0 to 1.0) | 1.0 (1.0 to 1.1) | 1.0 (1.0 to 1.0) | 1.0 (1.0 to 1.0) |
| 21 days after Prime Immunization (Day 22) | 1.2 (0.9 to 1.7) | 5.2 (2.8 to 9.7) | 1.8 (1.2 to 2.7) | 2.4 (1.5 to 4.0) |
| 7 days after Boost Immunization (Day 29) | 10.3 (5.3 to 20.1) | 95.6 (60.1 to 153.1) | 21.4 (11.6 to 39.2) | 2.0 (1.3 to 3.1) |
| 14 days after Boost Immunization (Day 36) | 12.1 (6.7 to 22.0) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 2.1 (1.4 to 3.1) |
| 21 days after Boost Immunization (Day 43) | 7.3 (4.0 to 13.2) | 23.3 (15.9 to 34.1) | 40.3 (21.0 to 77.4) | 1.9 (1.1 to 3.3) |
| 28 days after Boost Immunization (Day 50) | 6.3 (3.7 to 10.9) | 16.0 (9.8 to 26.1) | 44.0 (23.5 to 82.2) | 1.6 (1.0 to 2.5) |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|--|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 7 days after Prime Immunization (Day 8) | 1.0 (1.0 to 1.0) | 1.0 (1.0 to 1.0) | 1.3 (0.8 to 2.1) | 1.0 (1.0 to 1.0) |
| 21 days after Prime Immunization (Day 22) | 1.3 (1.0 to 1.7) | 1.1 (1.0 to 1.2) | 2.6 (1.3 to 5.0) | 1.9 (1.1 to 3.3) |
| 7 days after Boost Immunization (Day 29) | 10.7 (5.0 to 22.7) | 10.4 (5.0 to 21.5) | 55.4 (35.5 to 86.4) | 41.5 (23.6 to 73.0) |
| 14 days after Boost Immunization (Day 36) | 15.5 (8.1 to 29.9) | 44.0 (29.7 to 65.1) | 55.4 (31.2 to 98.4) | 71.8 (40.8 to 126.5) |
| 21 days after Boost Immunization (Day 43) | 10.7 (5.5 to 20.7) | 31.1 (21.0 to 46.0) | 49.4 (29.7 to 81.9) | 52.3 (27.2 to 100.5) |
| 28 days after Boost Immunization (Day 50) | 8.2 (4.1 to 16.6) | 27.7 (17.6 to 43.6) | 40.3 (26.7 to 60.9) | 39.2 (21.9 to 70.1) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

| | |
|-----------------|--|
| End point title | Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline |
|-----------------|--|

End point description:

At 7 and 21 days after primary immunization and at 7, 14, 21, and 28 days after the boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates missing Day 36 data of 10 µg and 20 µg younger cohort as they have only re-consented to Clinical Trial Protocol 7.0 (introducing visit 5a/Day 36) on/after their Day 43.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 50 days following first IMP dose

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| 7 days after Prime Immunization (Day 8) | 0 | 0 | 0 | 0 |
| 21 days after Prime Immunization (Day 22) | 1 | 9 | 2 | 5 |
| 7 days after Boost Immunization (Day 29) | 9 | 12 | 12 | 3 |
| 14 days after Boost Immunization (Day 36) | 9 | 9999 | 9999 | 4 |
| 21 days after Boost Immunization (Day 43) | 8 | 12 | 12 | 3 |
| 28 days after Boost Immunization (Day 50) | 8 | 11 | 12 | 1 |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| 7 days after Prime Immunization (Day 8) | 0 | 0 | 1 | 0 |
| 21 days after Prime Immunization (Day 22) | 1 | 0 | 4 | 2 |
| 7 days after Boost Immunization (Day 29) | 10 | 10 | 12 | 12 |
| 14 days after Boost Immunization (Day 36) | 11 | 12 | 12 | 12 |
| 21 days after Boost Immunization (Day 43) | 9 | 12 | 12 | 12 |
| 28 days after Boost Immunization (Day 50) | 9 | 12 | 12 | 12 |

Statistical analyses

No statistical analyses for this end point

Secondary: Functional Antibody Responses

End point title Functional Antibody Responses

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study vaccination or due to premature discontinuation. 99999 indicates value not evaluable, confidence intervals were only calculated if values of at least 3 participants were available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From 51 to up to 387 days following first IMP dose

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 63 days after Boost Immunization (Day 85) | 40.0 (22.4 to 71.4) | 51.9 (39.1 to 68.9) | 116.5 (51.0 to 266.1) | 13.0 (7.8 to 21.5) |
| 162 days after Boost Immunization (Day 184) | 11.7 (5.8 to 23.8) | 51.5 (33.9 to 78.1) | 119.9 (62.6 to 229.5) | 11.0 (4.7 to 25.8) |
| 365 days after Boost Immunization (Day 387) | 197.0 (14.2 to 2727.9) | 452.5 (47.4 to 4322.3) | 513.3 (215.8 to 1221.2) | 5.0 (-99999 to 99999) |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 63 days after Boost Immunization (Day 85) | 34.6 (18.1 to 66.1) | 85.2 (48.7 to 149.0) | 142.5 (77.9 to 260.7) | 75.5 (45.6 to 125.0) |
| 162 days after Boost Immunization (Day 184) | 9.6 (6.1 to 15.0) | 28.3 (11.2 to 71.6) | 44.9 (22.0 to 91.8) | 107.7 (42.3 to 273.8) |
| 365 days after Boost Immunization (Day 387) | 1280.0 (-99999 to 99999) | 9999 (-9999 to 9999) | 9999 (-9999 to 9999) | 9999 (-9999 to 9999) |

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Increase in Functional Antibody Titers

| | |
|-----------------|---|
| End point title | Fold Increase in Functional Antibody Titers |
|-----------------|---|

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study vaccination or due to premature discontinuation. 99999 indicates value not evaluable, confidence intervals were only calculated if values of at least 3 participants were available.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From 51 to up to 387 days following first IMP dose

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 63 days after Boost Immunization (Day 85) | 8.0 (4.5 to 14.3) | 10.4 (7.8 to 13.8) | 23.3 (10.2 to 53.2) | 2.6 (1.6 to 4.3) |
| 162 days after Boost Immunization (Day 184) | 2.3 (1.2 to 4.8) | 10.3 (6.8 to 15.6) | 24.0 (12.5 to 45.9) | 2.2 (0.9 to 5.2) |
| 365 days after Boost Immunization (Day 387) | 39.4 (2.8 to 545.6) | 90.5 (9.5 to 864.5) | 102.7 (43.2 to 244.2) | 1.0 (-99999 to 99999) |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| 63 days after Boost Immunization (Day 85) | 6.9 (3.6 to 13.2) | 17.0 (9.7 to 29.8) | 24.7 (15.3 to 39.9) | 15.1 (9.1 to 25.0) |
| 162 days after Boost Immunization (Day 184) | 1.9 (1.2 to 3.0) | 5.7 (2.2 to 14.3) | 9.0 (4.4 to 18.4) | 21.5 (8.5 to 54.8) |
| 365 days after Boost Immunization (Day 387) | 256.0 (-99999 to 99999) | 9999 (-9999 to 9999) | 9999 (-9999 to 9999) | 9999 (-9999 to 9999) |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline

| | |
|-----------------|--|
| End point title | Number of Participants With Seroconversion Defined as a Minimum of 4-fold Increase of Functional Antibody Titers as Compared to Baseline |
|-----------------|--|

End point description:

At 63, 162, 365 days after boost immunization. Immunogenicity set - all participants who received at least one dose of IMP and had at least one post-baseline functional antibody titer immunogenicity assessment. Boost immunization withheld for 30 µg younger cohort following Safety Review Committee decision. 9999 indicates Day 387 data is either missing due to exclusion because of non-study

vaccination or due to premature discontinuation.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From 51 to up to 387 days following first IMP dose | |

| End point values | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg | Part A Participants Aged 18 to 55 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| 63 days after Boost Immunization (Day 85) | 9 | 12 | 11 | 3 |
| 162 days after Boost Immunization (Day 184) | 4 | 11 | 12 | 2 |
| 365 days after Boost Immunization (Day 387) | 4 | 5 | 11 | 0 |

| End point values | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg |
|---|---|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 12 | 12 | 12 | 12 |
| Units: Participants | | | | |
| 63 days after Boost Immunization (Day 85) | 8 | 11 | 12 | 12 |
| 162 days after Boost Immunization (Day 184) | 2 | 6 | 6 | 6 |
| 365 days after Boost Immunization (Day 387) | 1 | 9999 | 9999 | 9999 |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Day 1 (Prime Immunization) up to Day 50 (with or without Boost Immunization). Adverse events with an onset date more than 28 days after the last administration of IMP are reported only if assessed as related to IMP by the investigator.

Adverse event reporting additional description:

Treatment emergent adverse events (TEAEs) are reported, i.e., adverse events (AEs) with an onset date on or after the first administration of IMP (if the AE was absent before the first administration of IMP) or worsened after the first administration of IMP (if the AE was present before the first administration of IMP).

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 23.1 |

Reporting groups

| | |
|-----------------------|--|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 3 µg |
|-----------------------|--|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 10 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 20 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 18 to 55 Years - 30 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime regimen only, as decided by the Safety Review Committee).

| | |
|-----------------------|--|
| Reporting group title | Part A Participants Aged 56 to 85 Years - 3 µg |
|-----------------------|--|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 56 to 85 Years - 10 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 56 to 85 Years - 20 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| | |
|-----------------------|---|
| Reporting group title | Part A Participants Aged 56 to 85 Years - 30 µg |
|-----------------------|---|

Reporting group description:

BNT162b3: Anti-viral RNA vaccine for active immunization against COVID-19 administered as intramuscular injection (Prime/Boost [P/B] regimen)

| Serious adverse events | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg |
|---|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| Serious adverse events | Part A Participants Aged 18 to 55 Years - 30 µg | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg |
|---|---|--|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| Serious adverse events | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg | |
|---|---|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |

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

| Non-serious adverse events | Part A Participants Aged 18 to 55 Years - 3 µg | Part A Participants Aged 18 to 55 Years - 10 µg | Part A Participants Aged 18 to 55 Years - 20 µg |
|---|--|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 12 (58.33%) | 4 / 12 (33.33%) | 5 / 12 (41.67%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Surgical and medical procedures | | | |
| Dental care | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| General disorders and administration site conditions | | | |

| | | | |
|---|----------------|----------------|----------------|
| Chest pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Fatigue | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|--|---------------------|----------------------|----------------------|
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Psychiatric disorders Restlessness subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Sleep disorder subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Investigations Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Lipase increased subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Injury, poisoning and procedural complications Skin laceration subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Cardiac disorders Palpitations subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 2 / 12 (16.67%) 2 | 2 / 12 (16.67%) 2 |
| Hyperaesthesia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Sciatica | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Vertigo | | | |
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Eye disorders | | | |
| Meibomian gland dysfunction | | | |
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Dyspepsia | | | |
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Flatulence | | | |
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Toothache | | | |
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Myalgia | | | |

| | | | |
|--|----------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 2 / 12 (16.67%) 2 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Myofascial pain syndrome subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Pain in extremity subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Infections and infestations | | | |
| Cystitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Oral herpes subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 |
| Pulpitis dental subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Sinusitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Urinary tract infection subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |

| Non-serious adverse events | Part A Participants Aged 18 to 55 Years - 30 µg | Part A Participants Aged 56 to 85 Years - 3 µg | Part A Participants Aged 56 to 85 Years - 10 µg |
|---|---|--|---|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 6 / 12 (50.00%) | 7 / 12 (58.33%) | 5 / 12 (41.67%) |
| Vascular disorders | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| Hypertension subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Surgical and medical procedures Dental care subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Influenza like illness subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Injection site reaction subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 |
| Malaise subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Tenderness subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|--|----------------|----------------|----------------|
| Cough | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Nasal discomfort | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Restlessness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Sleep disorder | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lipase increased | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cardiac disorders | | | |
| Palpitations | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |

| | | | |
|--|-----------------|----------------|----------------|
| Dizziness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 1 / 12 (8.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Headache | | | |
| subjects affected / exposed | 3 / 12 (25.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Hyperaesthesia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Meibomian gland dysfunction | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Flatulence | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Paraesthesia oral | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Toothache | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|----------------|-----------------|----------------|
| Pruritus | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 2 / 12 (16.67%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myofascial pain syndrome | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Cystitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 12 (8.33%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | 0 / 12 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| Non-serious adverse events | Part A Participants Aged 56 to 85 Years - 20 µg | Part A Participants Aged 56 to 85 Years - 30 µg | |
|---|---|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 5 / 12 (41.67%) | 6 / 12 (50.00%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Surgical and medical procedures | | | |
| Dental care | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Malaise | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 1 / 12 (8.33%) | |
| occurrences (all) | 0 | 1 | |
| Tenderness | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Immune system disorders | | | |
| Seasonal allergy | | | |

| | | | |
|---|---|---|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Nasal discomfort subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | 2 / 12 (16.67%) 4 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 | |
| Psychiatric disorders Restlessness subjects affected / exposed occurrences (all) Sleep disorder subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Investigations Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all) Lipase increased subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|--|--|
| Skin laceration subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Cardiac disorders Palpitations subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Nervous system disorders Dizziness subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Hyperaesthesia subjects affected / exposed occurrences (all) Sciatica subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 | |
| Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all) Vertigo subjects affected / exposed occurrences (all) | 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 | |
| Eye disorders Meibomian gland dysfunction subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Gastrointestinal disorders Dyspepsia subjects affected / exposed occurrences (all) Flatulence | 1 / 12 (8.33%) 1 | 0 / 12 (0.00%) 0 | |

| | | | |
|---|---------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Paraesthesia oral subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Toothache subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Myalgia subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Myofascial pain syndrome subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Pain in extremity subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 1 / 12 (8.33%) 1 | |
| Infections and infestations Cystitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Oral herpes subjects affected / exposed occurrences (all) | 0 / 12 (0.00%) 0 | 0 / 12 (0.00%) 0 | |
| Pulpitis dental | | | |

| | | | |
|-----------------------------|----------------|----------------|--|
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 12 (0.00%) | 0 / 12 (0.00%) | |
| occurrences (all) | 0 | 0 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|--|
| 15 September 2020 | This amendment described changes made to clarify potential inconsistencies, to align trial reporting with other ongoing BNT162 trials, and to enhance assessments for immunogenicity. |
| 02 December 2020 | This update implemented: a change in sponsor name; the addition of two additional dosing cohorts in older adults; measures to avoid under reporting of mild COVID-19 related events revealed within the trial; terminology alignment with other ongoing trials; correction to some errors. The rationale for the addition of two older adult cohorts was based on the available immunogenicity and cell-mediated immune response data after dosing with BNT162b1 and BNT162b2 in younger and elderly adults in the BNT162-01 (2020-001038-36) and BNT162-02 (2020-002641-42) trials elicited measurable but lower responses in elderly adults than in younger adults. Therefore, the additional older adult cohorts were to be used to investigate BNT162b3 doses above the already tested 20 µg BNT162b3 dose, to support any future Phase III program planned to support marketing approval. |
| 25 March 2021 | This update implemented the removal of Part B, changes to the primary objective endpoints, and a change to concomitant medication reporting during study follow-up to allow capture of vaccinations, e.g., SARS-CoV-2 vaccinations. |
| 12 May 2021 | This update implemented corrections to time points in the exploratory objectives and a deletion within Section 4.4 (End of Treatment and end of trial definition) in order to allow subjects to participate in other clinical trials investigating COVID-19 vaccines and treatments. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported