

The response after the first and second dose of the BNT162b2 Covid-19 vaccine: real-world evidence from Greece

Submission date 08/02/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

mRNA vaccines are a new type of vaccine to protect against infectious diseases. To trigger an immune response, many vaccines put a weakened or inactivated germ into our bodies. Not mRNA vaccines. Instead, they teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected if the real virus enters our bodies. The aim of this study is to enhance insight into the immunity and antibody generation elicited by the first and second dose of the BNT162b2 mRNA Covid-19 vaccine.

Who can participate?

Adult healthcare workers aged 18 - 69 years. Our study population includes both uninfected vaccinated persons and persons with PCR-confirmed previous SARS-CoV-2 infection occurring one to 4.5 months prior to vaccination.

What does the study involve?

Healthcare workers vaccinated in the two vaccination centers of the “G. Gennimatas” General Hospital of Thessaloniki will be followed for one year post-injection of the second dose of the vaccine.

What are the possible benefits and risks of participating?

None

Where is the study run from?

“G. Gennimatas” General Hospital of Thessaloniki (Greece)

When is the study starting and how long is it expected to run for?

December 2020 to March 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
Georgios Papazisis, papazisg@auth.gr

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Immunogenicity after the first and second dose of the BNT162b2 mRNA Covid-19 vaccine: real-world evidence from Greece

Acronym
GREVACIM

Study objectives
Several prophylactic vaccines against SARS-CoV-2 were recently launched after solid proof of their efficacy and safety was provided by clinical trials. However, real world data on the immunogenicity of these vaccines remain scarce. Our study aims at enhancing current insight into the humoral immunity and neutralizing antibody generation elicited by the first and second

dose of the BNT162b2 mRNA Covid-19 vaccine. For that matter, we measured the concentration of specific anti-SARS-CoV-2 IgGs acting against the receptor-binding domain (RBD) of the S1 subunit of the viral spike protein, performing a chemiluminescent microparticle immunoassay.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/01/2021, Ethics committee of the scientific council of the G. Gennimatas General Hospital (Ethnikis Aminis 41, postal code 54631, Thessaloniki, Greece; +30 2310963179; Konstantinakontopoulou9@gmail.com), ref: 1/13.1.2021

Study design

Observational prospective single-center study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

BNT162b2 mRNA COVID-19 vaccine immunogenicity among healthcare workers

Interventions

Based on the national prioritization scheme, healthcare providers were the first population group to receive the BNT162b2 mRNA Covid-19 vaccine in Greece. The first cohort of healthcare workers vaccinated in the two vaccination centers of the "G. Gennimatas" General Hospital of Thessaloniki will be followed for one year post-injection of the second dose of the vaccine. The titers of anti-SARS-CoV-2 antigen-specific IgGs will be monitored 14 days after the first dose and 14 days, 3, 6, 9 and 12 months after the second dose. The SARS-CoV-2 IgG II Quant assay on the ARCHITECT System will be conducted on participant-derived serum samples. Reactogenicity data regarding the BNT162b2 mRNA Covid-19 vaccine will also be collected.

Intervention Type

Biological/Vaccine

Phase

Phase IV

Drug/device/biological/vaccine name(s)

BNT162b2 mRNA COVID-19 vaccine

Primary outcome measure

Immunogenicity of the BNT162b2 mRNA Covid-19 vaccine measured using the SARS-CoV-2 IgG II Quant assay to conduct a qualitative and quantitative determination of IgGs against the receptor-binding domain (RBD) of the S1 subunit of the SARS-CoV-2 spike protein on day 14 after the first dose, day 14 after the second dose and within 3, 6, 9 and 12 months after the second dose.

Secondary outcome measures

1. PCR-confirmed cases of SARS-CoV-2 infection anytime after the first dose measured using hospital records
2. Reactogenicity monitored through adverse drug reaction reporting forms completed on day 14 after the first dose, day 14 after the second dose and within 3, 6, 9 and 12 months after the second dose

Overall study start date

20/12/2020

Completion date

30/03/2022

Eligibility

Key inclusion criteria

1. Age of 18 - 69 years
2. Without previously known SARS-CoV-2 infection, or
3. With previous PCR-confirmed SARS-CoV-2 infection one to 4.5 months prior to vaccination

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Upper age limit

69 Years

Sex

Both

Target number of participants

All healthcare workers of the G. Gennimatas hospital eligible for vaccination based on the national vaccination scheme: target number 450

Total final enrolment

425

Key exclusion criteria

1. Occurrence of any other vaccination 4 weeks prior to enrollment
2. Pregnancy or breastfeeding
3. Participation in any other clinical trial

Date of first enrolment

25/01/2021

Date of final enrolment

28/02/2022

Locations**Countries of recruitment**

Greece

Study participating centre

Georgios Gennimatas General Hospital

Eth. Aminis 41

Thessaloniki

Greece

54635

Sponsor information**Organisation**

Georgios Gennimatas General Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/02j61yw88>

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publications in a high-impact peer-reviewed journal and a plan to publish interim analysis results 14 days after the first dose (February 2021), 14 days after the second dose (April 2021) and one year after the second dose (April 2022).

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Completely anonymised, de-identified (stripped of all “direct identifiers”) numerical data in spreadsheets will be shared with researchers from the academia and relevant research institutions after the publication of corresponding results in peer-reviewed academic journals, for purposes of independent statistical analysis and verification of results. Participants provided consent for the use of anonymised data for research purposes.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2021	06/03/2024	Yes	No
Results article		30/05/2022	06/03/2024	Yes	No