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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

Registration date
10/02/2021

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
69 years

Sex
All

Total final enrolment
425

Key exclusion criteria
1. Occurence 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

ROR
https://ror.org/02j61yw88

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

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