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Immune response to the BNT162b2 vaccine against the COVID-19 virus in healthcare workers and immunocompromised patients

Submission date
22/02/2021

Recruitment status
No longer recruiting

Registration date
24/02/2021

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others (asymptomatic). People who have developed the condition may develop a fever and/or a continuous cough among other symptoms (symptomatic). This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

Since the first cases of COVID-19 were described in December, a health emergency with major social and economic disruptions has spread worldwide. The World Health Organization, on the 11th of March 2020, announced the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) outbreak a pandemic. Control measures such as the use of masks, physical distancing, and contact tracing, helped to limit viral transmission. Since the genetic sequence of SARS-CoV-2 on January 11, 2020, scientists and biopharmaceutical manufacturers focused their research on developing a vaccine.

Currently, there are over 238 vaccine candidates being developed against COVID-19, with 63 at various stages of human clinical trial testing. A large clinical trial with 44,000 people showed that a two-dose regimen of the vaccine BNT162b2, developed by BioNTech and Pfizer, has 95% efficacy in preventing symptomatic COVID-19. The same study showed that the safety of BNT162b2 was similar to that of other vaccines over an average of 2 months. As a consequence of these results, on December 11th, 2020, the U.S. Food and Drug Administration authorized vaccine BNT162b2 for emergency use. This was soon followed by the European Medicines Agency on 21 December 2020.

The vaccine includes the genetic material (mRNA) of the virus that causes COVID-19 that is used to make proteins of the virus. After vaccination, the immune system recognizes that the COVID-

19 proteins which do not belong in the body and begins making white blood cells and proteins called antibodies which target the proteins coded by the mRNA of the vaccine and therefore fight COVID-19 infection.

The effectiveness of the BNT162b2 vaccine against COVID-19 infection has not yet been established and more data is certainly needed to assess the effect on the immune system of the vaccine and how effectively it can protect against the virus.

The first goal of this study is to analyze the presence of antibodies after the second dose of BNT162b2 vaccine in health-care-workers and cancer patients or other immunocompromised patients at the Istituti Fisioterapici Ospitalieri (IFO). The second goal is to analyze the protection against SARS-CoV-2 infections of health-care-workers and immunocompromised patients at the IFO who have received the vaccine. The third goal is to analyze the antibody response in correlation with age, gender, and BMI.

Who can participate?
Health-care-workers and cancer patients or other immunocompromised patients at the Istituti Fisioterapici Ospitalieri

What does the study involve?
Participants will receive the mRNA vaccine as an injection into the muscle of the upper arm on days 1 and 22 of the study. Participants will be assessed for the presence of antibodies against COVID-19 using a blood test, and for COVID-19 infection using a swab of the throat and nose, before the first dose of the vaccine, after 22 and 28 days, and then every 30 days until the end of the study.

What are the possible benefits and risks of participating?
The main benefit for participants is protection from SARS-CoV-2 infection. Any risks are related to vaccine adverse effects. Both the benefits and risks of this vaccine have been reported in previous studies.

Where is the study run from?
Istituti Fisioterapici Ospitalieri (Italy)

When is the study starting and how long is it expected to run for?
From December 2020 to January 2023

Who is funding the study?
Istituti Fisioterapici Ospitalieri (Italy)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
protocol RS1463/21

Study information

Scientific Title
Study of immunogenicity and effectiveness of BNT162b2 in healthcare workers and oncological /immunocompromised patients at Istituti Fisioterapici Ospitalieri.

Acronym
SIFO

Study objectives
To evaluate the presence of antibodies against Spike's S1 and S2 subunits following the BNT162b2 vaccine and its effectiveness in protecting against SARS-CoV-2 infections in health-care-workers and oncological/immunocompromised patients at the Istituti Fisioterapici Ospitalieri.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/01/2021, Comitato Etico Centrale IRCCS Lazio (via Elio Chianesi 53, 00144 Rome, Italy; +39 (0)652662719; anna.dambrosio@ifo.gov.it), ref: 1463/21

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection) in health-care-workers and oncological/immunocompromised patients

Interventions
Data on the participants' sociodemographic and health characteristics will be collected using a questionnaire, and participants will be stratified by age, sex, and body mass index (BMI).

The mRNA vaccine will be administered to all participants as a 30 µg/0.3 ml intramuscular injection into the deltoid on days 1 and 22 of the study.

Participants will be assessed for the presence of SARS-CoV-2–binding antibodies (The LIAISON® SARS-CoV-2 S1/S2 IgG, test Diasorin, Italy) and will have a nasopharyngeal swab for SARS-CoV-2 RT-PCR testing (Viracor, Eurofins Clinical Diagnostics, U.S.A.) at baseline, 22 and 28 days after the BNT162b2 priming dose. Thereafter nasopharyngeal swab and blood collection will be undertaken every 30 days until the end of the study (until 26/01/2023).

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tozinameran vaccine (BNT162b2)

Primary outcome(s)
1. Presence of antibodies measured using blood tests analysed by the LIAISON® SARS-CoV-2 S1 /S2 IgG, test at baseline, 22 and 28 days, and every 30 days until the end of the study

Key secondary outcome(s))
1. SARS-CoV-2 infection measured using a nasopharyngeal swab analysed by SARS-CoV-2 RT-PCR testing at baseline, 22 and 28 days, and every 30 days until the end of the study

Completion date
23/02/2023

Eligibility

Key inclusion criteria
1. Provided written informed consent
2. Oncological/immunocompromised patient at the Istituti Fisioterapici Ospitalieri (IFO) or health worker employed at the Istituti Fisioterapici Ospitalieri
3. Vaccinated at the Istituti Fisioterapici Ospitalieri

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Evidence of current or previous SARS-CoV-2 infection by either anamnesis, serological or microbiological test through nasopharyngeal swab before enrolment

Date of first enrolment
27/01/2021

Date of final enrolment
26/01/2023

Locations

Countries of recruitment
Italy

Study participating centre
Istituti Fisioterapici Ospitalieri
Via Elio Chianesi 54
Rome
Italy
00144

Sponsor information

Organisation
Istituti Fisioterapici Ospitalieri

ROR
https://ror.org/04j6jb515

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IFO Istituti Fisioterapici Ospitalieri

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/10/2021	06/03/2024	Yes	No
Other publications	Correlation with age, gender and BMI	22/06/2021	05/08/2021	Yes	No
Other publications	Effect of age, gender and BMI on vaccine response	04/06/2021	05/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint (other)	Effect of age, gender and BMI on vaccine response	26/02/2021	05/08/2021	No	No