Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Oct 2026

Comparison of humoral response in half and full dose of BNT162b2 vaccinated in people under 55 years of age

Protocol summary

Study aim

The aim of this study is confirm that in adults up to 55 years old, the humoral response to the half-dose (15ug) and to the standard dose (30ug) in the two-dose three-week interval schedule would be comparable since half-dose schedule can help limit achieve wide vaccination coverage more quickly and cheaply.

Design

Two arm parallel group not randomised and not blinded single center trial.

Settings and conduct

All participant had the antibody levels measured prior do the first dose of the vaccine. Participants with a positive result were included in the prior COVID-19 infection group and had another antibody measurement on day 8 after the first vaccine dose. Participants with a negative result were included in the no-prior COVID-19 infection group and had antibody levels measured on day 21 after first vaccine dose and day 8 after second vaccine dose.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Willingness to take part in the clinical trial -Age between 18 and 55 years old Exclusion criteria: -Age above 55 years old -Diagnosed with diabetes, hypertension, heart disease, chronic pulmonary diseases, severe allergies -Obesity as defined by BMI > 30

Intervention groups

Healthy participants aged 18-55 received half-dose (15ug) (HD) and were compared to subjects of similar age who received the full 30ug dose (FD) and were monitored as part of a parallel study (Bioethics Committee opinion at the Regional Medical Chamber in Gdansk KB-4/21).

Main outcome variables

Prior COVID-19 infection: -Antibody level on day 8 after first vaccine dose No prior COVID-19 infection: -Antibody levels on day 21 after first vaccine dose and day 8 after second vaccine dose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210708051820N1**
Registration date: **2021-08-06, 1400/05/15**
Registration timing: **retrospective**

Last update: **2021-08-06, 1400/05/15**
Update count: **0**

Registration date

2021-08-06, 1400/05/15

Registrant information

Name
Amira Podolak
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Invicta Research and Development Center
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Poland
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-27, 1399/11/08

Expected recruitment end date

2021-04-30, 1400/02/10

Actual recruitment start date

2021-02-01, 1399/11/13

Actual recruitment end date

2021-04-29, 1400/02/09

Trial completion date

2021-05-21, 1400/02/31

Scientific title
Comparison of humoral response in half and full dose of BNT162b2 vaccinated in people under 55 years of age

Public title
Biding antibodies in half and full dose BNT162b2 vaccinated people under 55 years of age

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to take part in the clinical trial Age between 18 and 55 years old

Exclusion criteria:
Age above 55 years old Diagnosed with diabetes, hypertension, heart disease, chronic pulmonary diseases, severe allergies Obesity as defined by BMI > 30

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **35**
Actual sample size reached: **42**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee at the Gdansk Regional Medical Board

Street address
Śniadeckich 33

City
Gdańsk

Postal code
80-204

Approval date
2021-03-30, 1400/01/10

Ethics committee reference number
No KB - 4/21 and KB – 14/21

Health conditions studied

1

Description of health condition studied
The humoral response to the half-dose of BNT162b2-vaccine.

ICD-10 code
T80.62

ICD-10 code description
Other serum reaction due to vaccination

Primary outcomes

1

Description
Anti-SARS-CoV-2 antibody level

Timepoint
On the day of dose-2 of the vaccine and 8-10 days later

Method of measurement
IVD Elecsys Anti-SARS-CoV-2 S assay (Roche Diagnostics)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vaccination with BNT162b2 vaccine (Comirnaty, Pfizer/BioNTech), 2 doses at 15ug each, dose interval 21 days. Blood draws for antibody testing: day 1, 8, 21, 28-30 (day 1 is the day of the first dose of the vaccine)

Category
Prevention

2

Description
Control group: Vaccination with BNT162b2 vaccine (Comirnaty, Pfizer/BioNTech), 2 doses at 30ug each, dose interval 21 days. Blood draws for antibody testing: day 1, 8, 21, 28-30 (day 1 is the day of the first dose of the vaccine)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
INVICTA Research and Developmend Center

Full name of responsible person
Krzysztof Łukaszuk

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Anna Knight
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anna.knight@invicta.pl
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Invicta Research and Development Center
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Invicta Research and Development Center
Full name of responsible person
Krzysztof Łukaszuk
Position
Professor
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Person responsible for updating data

Contact
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Researcher
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Deidentified data can be made available upon request
When the data will become available and for how long
Data can be made available starting 6 months after the trial result are published
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Requests will be reviewed on the case-by-case basis.
From where data/document is obtainable
Requests should be sent to anna.knight@invicta.pl
What processes are involved for a request to access data/document
Requests will be reviewed on the case-by-case basis.
Requests should included the proposed use of data.
Comments