Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the humoral response in patients receiving half doses of AstraZeneca and BNT162b2 vaccines in a heterogenous prime-boost schedule.

Protocol summary

Study aim

The aim of this study is to confirm that the humoral response in patients receiving half doses of AstraZeneca and BNT162b2 vaccines in a heterogenous prime-boost schedule would be comparable to those receiving two full doses of the same vaccine (BNT162b2).

Design

Two arm parallel group not randomized and not blinded single-center trial.

Settings and conduct

Some of participants were initially vaccinated with BNT162b2 and the rest of them with AstraZeneca vaccine. The second dose of the vaccine - different than the first time - was given between 21 and 28 days after dose-1. Each participant had blood drawn on the day of the dose-2 and 8-10 days after dose-2 and antibody levels measured (Roche Elecsys Anti-SARS-CoV-2 S IVD kit). The reference group included individuals undergoing vaccination with two full doses of BNT162b2 vaccine (21-day interval) monitored for their antibody levels as part of a parallel study.

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 were initially vaccinated with half-dose AstraZeneca (0.25ml) or half-dose BNT162b2 (0.15ml) vaccine and received the second vaccination between 21 and 28 days after dose-1 with half-dose vaccine different than the first time. Results were compared to subjects of similar age who received two full doses of BNT162b2 (0.3ml) and were monitored as part of a parallel study.

Main outcome variables

Measurement of the humoral response based on IVD sets (Elecsys Anti-SARS-CoV-2 S assay - Roche Diagnostics) for determining the level of mature antibodies against Sars-CoV-2 virus protein.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210801052044N1**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **retrospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

Registration date

2021-08-29, 1400/06/07

Registrant information

Name

Paulina Malinowska

Name of organization / entity

Invicta Research and Development Center

Country

Poland

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-30, 1400/01/10

Expected recruitment end date

2021-04-30, 1400/02/10

Actual recruitment start date
2021-03-30, 1400/01/10
Actual recruitment end date
2021-04-30, 1400/02/10
Trial completion date
2021-07-21, 1400/04/30

Scientific title
Evaluation of the humoral response in patients receiving half doses of AstraZeneca and BNT162b2 vaccines in a heterogenous prime-boost schedule.

Public title
Evaluation of the humoral response in patients receiving half doses of AstraZeneca and BNT162b2 vaccines in a heterogenous prime-boost schedule.
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 pulmonarydiseases, 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: **20**
Actual sample size reached: **26**
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
Gdansk
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-doses of AstraZeneca and BNT162b2 vaccines in a heterogenous prime-boost schedule.
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
Category
Prevention

2

Description
Control group: Vaccination with BNT162b2 vaccine (Comirnaty,Pfizer/BioNTech), 2 full doses (0,3ml), dose interval 21 days. Blood draws for antibody testing: the day of the dose-2 and 8-10 days later
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center

INVICTA Research and Developmend Center
Full name of responsible person
Krzysztof Lukaszuk
Street address
Polna 64
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sekretariatlukaszuk@invicta.pl

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Academic

Person responsible for general inquiries

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

Contact
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Invicta Research and Development Center
Full name of responsible person
Paulina Malinowska
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Medical Laboratory Specialist
Latest degree
Master
Other areas of specialty/work
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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