Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

A randomized, two-armed, Placebo controlled (5:1), Double-blind, parallel clinical trial to compare the immunogenicity and safety of SpikoGen® vaccine (an adjuvanted recombinant spike (S) protein produced by CinnaGen Co.) as a booster dose

Protocol summary

Study aim
Assessing whether administration of the recombinant SARS-CoV-2-S protein vaccine (SpikoGen®) as a booster shot is immunogenic and safe

Design
A randomized,two-armed,Placebo controlled (5:1),Double-blind,parallel with 300 volunteers

Settings and conduct
A randomized,two-armed,Placebo controlled (5:1),Double-blind, parallel in Orchidlife department of Orchidpharmed Co.

Participants/Inclusion and exclusion criteria
Inclusion: Individuals older than 18 years; Participants who are able to comply with study requirements; Individuals who received two doses of the SARS-CoV-2 vaccine with each platform within 4 to 9 months prior to the screening visit; Healthy and stable medical conditions; Exclusion: Subjects with active infection with signs of SARS-COV-2 and 72 hours before the screening visit; People with a history of Covid -19 after 2 doses of vaccination; People with epilepsy or a history of febrile seizure; People who have receive immunosuppressive medications; People with a history of severe adverse reactions to the study vaccine; People who have participated in clinical trials within 30 days before screening until end of the study; People who have received other authorized vaccines within 28 days prior to the screening/intend to receive the vaccine up to 14 days after the second dose; People with the known bleeding disorder; Pregnant or breast-feeding women or women who plan to become pregnant up to 1 month after the booster dose; People with special circumstances who, in the researcher's view, may increase the risk of participating in the study; People who have received any blood/blood products 90 days prior to screening or during study; Peop;e who donated blood/blood products ≥450ml 28 days prior to screening.

Intervention groups
Intervention:1IM injection of 25 µg subunit vaccine with Advax-CpG adjuvant. Placebo:1IM injection of normal saline 0.9%

Main outcome variables
Comparison of seroconversion for neutralizing antibodies two weeks after the booster dose in both groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150303021315N26**
Registration date: **2021-12-12, 1400/09/21**
Registration timing: **prospective**

Last update: **2021-12-12, 1400/09/21**
Update count: **0**

Registration date
2021-12-12, 1400/09/21

Registrant information

Name
Nassim Anjidani

Name of organization / entity
Orchid Pharmed

Country
Iran (Islamic Republic of)

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+98 21 4347 3000

Email address
amini@orchidpharmed.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-16, 1400/09/25
Expected recruitment end date
2021-12-31, 1400/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomized, two-armed, Placebo controlled (5:1), Double-blind, parallel clinical trial to compare the immunogenicity and safety of SpikoGen® vaccine (an adjuvanted recombinant spike (S) protein produced by CinnaGen Co.) as a booster dose

Public title
Comparison of immunogenicity and safety of SpikoGen vaccine as booster dose
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Men or women older than 18 years Participants who are willing and able to comply with study requirements, including all scheduled visits, vaccinations, and tests Individuals who received two doses of the SARS-CoV-2 vaccine with each platform within 4 to 9 months prior to the screening visit Healthy adults or adults with stable medical conditions
Exclusion criteria:
Subjects with active infection with SARS-COV-2 signs at the screening visit and 72 hours before the screening visit People with a history of Covid -19 after 2 doses of vaccination People with epilepsy or a history of febrile seizures People who are being treated with immunosuppressive drugs. Among the cytotoxic agents or systemic corticosteroids, for example, for cancer, autoimmune disease or organ transplants or require a specific medical prescription during the study period. Receiving cytotoxic and chemotherapy drugs at any dose will prevent people from entering the study People who have a history of severe allergic reactions (eg anaphylaxis) to any components of the vaccine being studied or other drugs Individuals who have received any other research product within 30 days prior to screening visit or intend to participate in another clinical study at the time of this study Individuals who received other authorized vaccines (such as Influenza vaccine or Gardasil) within 28 days prior to the screening visit in this study or intend to receive each vaccine up to 14 days after the second vaccination People who have a known bleeding disorder and who, according to the researcher, may have problems with the intramuscular injection Pregnant or breast-feeding women or women who plan to become pregnant up to 1 month after the booster dose People who have received or intend to receive any blood / plasma or immunoglobulin products during the 90 days prior to the screening visit People with special circumstances who, in the researcher's view, may increase the risk of participating in the study or interfering with the evaluation of the initial objectives of the study People who have donated more than or equal to 450 ml of blood or blood products in the 28 days before the screening visit
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be assigned to treatment using permuted block randomization by R-CRAN-version 4.0.1. After randomization procedure, a code will be allocated to each patient that will be used as patient identifier throughout the study. The assigned code will be denoted by 4 initials (corresponding to the first two letters of first name, first two letters of surname) and 3 numbers (center code), first three letters of the generic name of the investigational product, i.e. VAC and three numbers (corresponding to the order in which the participant enters the study), e.g. ABCD001VAC-001.Randomization numbers are determined sequentially. Each vaccine syringe has a unique code that differs from the rest of the vaccines. The CRO is responsible for preparing the unique codes. Therefore, only the CRO knows each code for the vaccine (manufactured by CinnaGen) or placebo (0.9% normal saline). In case of enrollment, each subject will be given a randomization code and will be assigned to one of the groups. During each visit, a vaccine with a specific code will be given to the subject. The CRO will monitor how subjects are assigned to the treatment groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The vaccine and the placebo have the same research label and are suitable for the vaccine boxes and syringes. The contents of the labels are based on EMA regulation. The SpikoGen® vaccine or placebo are packaged in the same way. Unique codes are printed on the vaccine and placebo labels, and each vaccine is linked to the participant through this unique code Participants and medical staff are not aware of the vaccine or placebo. The type of participants group and the type of vaccine they received will not be known for investigators and will be stored in opaque sealed envelopes at the center. Decoding under special circumstances, is the responsibility of the DSMB Committee. Decoding for a participant is done by the

investigator of the center, when all of the possibilities in the occurrence of the event are evaluated and rejected. The vaccine or the placebo is recognized as the most important factor in the occurrence of an event or management of its complications which lead to special treatment for the participant and a decision that is not possible without decoding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran National Committee for Ethics in Biomedical Research

Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City
تهران

Province
Tehran

Postal code
1467664961

Approval date
2021-12-12, 1400/09/21

Ethics committee reference number
IR.NREC.1400.015

Health conditions studied

1

Description of health condition studied
Covid-19

ICD-10 code
U07.1

ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Comparison of seroconversion for neutralizing antibodies in two groups

Timepoint
two weeks after booster dose

Method of measurement
ELISA and statistical analysis

Secondary outcomes

1

Description
Occurrence of solicited adverse events

Timepoint
Up to 7 days after booster dose

Method of measurement
Checkup, history checking and participants reports based on adverse event reporting system

2

Description
Occurrence of unsolicited adverse events

Timepoint
Up to 14 days after booster dose

Method of measurement
Checkup, history checking and participants reports based on adverse event reporting system

3

Description
Incidence of Serious Adverse Event and Suspected Unexpected Serious Adverse Reactions

Timepoint
during 6 months after booster dose

Method of measurement
Checkup, history checking and participants reports based on adverse event reporting system

4

Description
Comparing GMC of antibodies against S protein

Timepoint
days 14,90,180

Method of measurement
ELISA test and statistical analysis

5

Description
Comparing GMFR of antibodies against S protein

Timepoint
two weeks after booster dose

Method of measurement
ELISA test and statistical analysis

6

Description
Comparison of seroconversion of antibodies against S1 protein

Timepoint
two weeks after booster dose

Method of measurement
ELISA test and statistical analysis

7

Description
Comparison of seroconversion antibodies against RBD protein in two groups
Timepoint
two weeks after booster dose
Method of measurement
ELISA test and statistical analysis

8

Description
Comparison of GMC for Antibody against RBD protein in two groups
Timepoint
days 14,90,180
Method of measurement
ELISA test and statistical analysis

9

Description
Comparison of GMFR for neutralizing antibodies against RBD in two groups
Timepoint
two weeks after booster dose
Method of measurement
ELISA test and statistical analysis

10

Description
Comparison of GMC for neutralizing antibodies against SARS-CoV-2 in two groups
Timepoint
days 14,90,180
Method of measurement
ELISA test and statistical analysis

11

Description
Comparison of GMFR for neutralizing antibodies against SARS-CoV-2 in two groups
Timepoint
two weeks after booster dose
Method of measurement
ELISA test and statistical analysis

12

Description
Evaluation of cellular immune response and Interferon Gamma release assay
Timepoint
days 0 and 14
Method of measurement
SARS-CoV-2 QuantiFERON Kit

Intervention groups

1

Description
Intervention group: Injecting one dose of 1 ml solution of SpikoGen® vaccine containing recombinant SARS-CoV-2-S protein and Advax™ and CpG adjuvants in the non-dominant arm
Category
Prevention

2

Description
Control group: Injecting one dose of 1 ml placebo containing normal saline (0.9% NaCl solution) in non-dominant arm
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Orchidlife Department in Orchidpharmed Co.
Full name of responsible person
Payam Tabarsi
Street address
No 42. Attar sq, attar st, valiasr st, vanak sq, Tehran, Iran
City
Tehran
Province
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Postal code
1994766411
Phone
+98 21 4347 3000
Email
ask@orchidpharmed.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
CinnaGen Company
Full name of responsible person
Dr. Haleh Hamedifar
Street address
No.72, CinnaGen research and production Company. Simin Dasht Industrial Park, Karaj, Alborz, Iran
City
Karaj
Province
Alborz
Postal code
3165933155
Phone
+98 26 3667 0980

Email
cinnagen@cinnagen.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
CinnaGen Company
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
Orchid Pharmed
Full name of responsible person
Nassim Anjidani
Position
Medical Department Manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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No 42. Attar sq, Attar st, Valiasr st, Vanak sq, Tehran, Iran
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1994766411
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anjidani.n@orchidpharmed.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Payam Tabarsi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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1956944413
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tabarsi@nritld.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Orchid Pharmed
Full name of responsible person
Nassim Anhidani
Position
Medical Department Manager
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
No 42. Attar sq, attar st, valiasr st, vanak sq, Tehran, Iran
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Participants' data will be available for regulatory and ethics committee for decisions.
When the data will become available and for how

long

Documents including study protocol and the results will be available to the public after the study ends.

To whom data/document is available

The regulatory body and the ethics committee will have access to the study data. The monitoring team will have access to the study data during the conduct. DSMB will have access to the study data and results in predefined timelines and decides about the continuation of the study.

Under which criteria data/document could be used

With the permission of the sponsor and the approval of regulatory

From where data/document is obtainable

The study sponsor is responding to this request

What processes are involved for a request to access data/document

After contacting the principal investigator and obtaining permission from the sponsor

Comments