Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A single armed, open label, clinical trial to evaluate the immunogenicity of SpikoGen® vaccine as booster dose (Spike protein, produced by CinnaGen company) in kidney transplant patients being fully vaccinated with Sinopharm vaccine

Protocol summary

Study aim
Evaluation immunogenicity of SpikoGen vaccine as booster dose in patients with a history of kidney transplantation and receiving 2 doses of Sinopharm

Design
A singe armed,open Label,non-randomized clinical trial in 100 kidney transplant patients who received two doses of sinopharm vaccine after transplantation

Settings and conduct
A singla-arm clinical trial in kidney transplant patients who received 2 doses of Sinopharm vaccine after transplantation will receive SpikoGen as booster dose in Shahid Labbafinejad Clinic. Blood samples are taken before and after the injection to check for immunogenicity

Participants/Inclusion and exclusion criteria
Inclusion:Men and women older than 18;Patients with history of kidney transplantation who vaccinated with two doses Sinopharm vaccine after transplantation;Women who are not pregnant or breast-feeding;People who have been transplanted for more than 6 months;Exclusion:Subjects with active infection with signs of SARS-COV-2 at screening visit;History of covid-19 based on a previous positive PCR;Treatment of active CMV infection;History of receiving rituximab during the past 6 months;History of receiving IVIg during the past 6 months;People with history of severe adverse reactions to the study vaccine;who participated in clinical trials within 30 days before screening until end of the study;History of transplant rejection during the past 30 days;Subjects with special circumstances who, may increase the risk of participating in the study according to researcher's opinion

Intervention groups
1IM injection of 25 µg Spikogen vaccine with Advax-CpG adjuvant

Main outcome variables
Evaluation of seroconversion in antibody against Spike protein one month after receiving booster dose; Evaluation of seroconversion in neutralizing antibodies one month after receiving booster dose

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150303021315N28**
Registration date: **2022-02-02, 1400/11/13**
Registration timing: **prospective**

Last update: **2022-02-02, 1400/11/13**
Update count: **0**

Registration date
2022-02-02, 1400/11/13

Registrant information
Name
Nassim Anjidani
Name of organization / entity
Orchid Pharmed
Country
Iran (Islamic Republic of)
Phone
+98 21 4347 3000
Email address
amini@orchidpharmed.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date
2022-03-16, 1400/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A single armed, open label, clinical trial to evaluate the immunogenicity of SpikoGen® vaccine as booster dose (Spike protein, produced by CinnaGen company) in kidney transplant patients being fully vaccinated with Sinopharm vaccine

Public title
SpikoGen® vaccine as booster dose in kidney transplant patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women older than 18 Patients with history of kidney transplantation who vaccinated with two doses Sinopharm vaccine after transplantation Women who are not pregnant or breast-feeding People who have been transplanted for more than 6 months

Exclusion criteria:
Subjects with active infection with signs of SARS-COV-2 at screening visit History of covid-19 based on a previous positive PCR Treatment of active Cytomegalovirus (CMV) infection History of receiving rituximab during the past 6 months History of receiving IVIg during the past 6 months Subjects who have a history of severe allergic reactions (e.g. anaphylaxis) to the study vaccine or any components of the vaccine or any other drugs Subjects who have received any other investigational product within 30 days prior to the screening visit or intend to participate in other clinical studies during this trial History of transplant rejection during the past 30 days Subjects with special circumstances who, may increase the risk of participating in the study or interfering with the evaluation of the primary endpoints of the study according to researcher's opinion

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urology and Nephrology Research Center-Shahid Beheshti university of medical sci

Street address
N0.103, 9th Boostan, Pasdaran Ave.

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-01-22, 1400/11/02

Ethics committee reference number
IR.SBMU.UNRC.REC.1400.017

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
Evaluation of seroconversion of antibody against spike protein

Timepoint
One month after booster dose

Method of measurement
ELISA and statistical analysis

2

Description
Evaluation of seroconversion of neutralizing antibodies

Timepoint
One month after booster dose

Method of measurement

ELISA and statistical analysis

Secondary outcomes

1

Description
Evaluation GMFR of antibodies against S protein
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

2

Description
Evaluation of GMFR for neutralizing antibodies
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

3

Description
Evaluation GMFR of antibody against S protein in subgroups with initial response and no initial response to Sinopharm vaccine
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

4

Description
Evaluation GMFR of neutralizing antibodies in subgroups with initial humoral response and no initial humoral response to Sinopharm vaccine
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

5

Description
Evaluation of seroconversion against S protein in subgroups with initial humoral response and no initial humoral response to Sinopharm vaccine
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

6

Description
Evaluation of seroconversion of neutralizing antibodies in subgroups with initial humoral response and no initial humoral response to Sinopharm vaccine
Timepoint
One month after booster dose
Method of measurement
ELISA test and statistical analysis

7

Description
Evaluation of cellular immune response
Timepoint
One month after booster dose
Method of measurement
SARS-CoV-2 QuantiFERON Kit

8

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

9

Description
Occurrence of unsolicited adverse events
Timepoint
One month after booster dose
Method of measurement
Checkup, history checking and participants reports based on adverse event reporting system

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Labbafinezhad clinic
Full name of responsible person
Mohsen Nafar
Street address
Between 8th Neyestan and 9th Boostan St, Pasdaran Ave.
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1666650003

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labafinejad.hos@tamin.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti university of medical sciences Urology and Nephrology Research Center
Full name of responsible person
Abbas Basiri
Street address
No.101, 9th Boostan, Pasdaran Ave.
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Province
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Postal code
1666677951
Phone
+98 21 2256 7222
Email
research@unrc.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti university of medical sciences Urology and Nephrology Research Center
Proportion provided by this source
100
Public or private sector
Public
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shiva Samavat
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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Person responsible for scientific inquiries

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Person responsible for updating data

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Others
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Email

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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.

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