

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Phase I, Randomized, Double Blind, Placebo-controlled, Study of the Safety and Immunogenicity of mRNA-based COVID-19 Vaccine (CORNAPCIN) Produced by ReNAP Co. as Booster Dose in Healthy Population Aged 18-50 Years

Protocol summary

Study aim

Safety and immunogenicity evaluation of mRNA-based COVID-19 vaccine (CORNAPCIN) produced by ReNAP Co. as booster dose in healthy population

Design

Phase I, randomized, double-blind, placebo-controlled, parallel group clinical trial in 30 healthy subjects

Settings and conduct

The study will be conducted as a randomized, double-blind, placebo-controlled trial in 30 healthy subjects at Mahdi Clinic in Tehran. Subjects will be randomly assigned to receive CORNAPCIN or placebo as a booster dose. Subjects then will be evaluated for adverse events and immunogenicity parameters within 6 months.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Aged 18 to 50 years; received 3 doses of Sinopharm or COVIran Barekat vaccine and time interval from last dose of vaccine to intervention at least 90 days and maximum 18 months; Body Mass Index: 18-35 kg/m²; In good health based on clinical and laboratory criteria; Consent to contraception up to sixty days after the intervention. Main exclusion criteria: Pregnancy or breastfeeding; Positive test for Hepatitis B, Hepatitis C, or HIV; History of blood coagulation disorders; Use of any medication that may be associated with impaired immune responsiveness; History of alcohol abuse or other drugs; History of hypersensitivity to any medication or other substances; Positive PCR test of COVID-19 or influenza or symptoms consistent with these diseases; History of COVID-19 diagnosis within the last 3 months; Vulnerable groups and foreigners

Intervention groups

Intervention group1: 25 ug CORNAPCIN; Intervention group2: 50 ug CORNAPCIN; Placebo group: Normal saline 0.9 %

Main outcome variables

Reactogenicity during 1 hour; Solicited adverse events (AEs) during 7 days; Unsolicited AEs during 28 days; SAEs, NOCMCs, and MAAEs during 181 days; CORNAPCIN right dose selection; SARS-CoV-2 specific antibodies, Cell mediated immunity and cytokines

General information

Reason for update

Recording the actual recruitment start and end date; Changing one of the inclusion criteria: Adding the COVIran Barekat vaccine to vaccination history and increasing the maximum time interval between receiving the third dose of vaccine to receiving clinical study intervention from 12 months to 18 months

Acronym

IRCT registration information

IRCT registration number: **IRCT20230131057293N1**
Registration date: **2023-02-07, 1401/11/18**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **1**

Registration date

2023-02-07, 1401/11/18

Registrant information

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Name of organization / entity

ReNAP Technology

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2023-02-08, 1401/11/19

Expected recruitment end date

2023-03-10, 1401/12/19

Actual recruitment start date

2023-02-21, 1401/12/02

Actual recruitment end date

2023-05-03, 1402/02/13

Trial completion date

empty

Scientific title

Phase I, Randomized, Double Blind, Placebo-controlled, Study of the Safety and Immunogenicity of mRNA-based COVID-19 Vaccine (CORNAPCIN) Produced by ReNAP Co. as Booster Dose in Healthy Population Aged 18-50 Years

Public title

Evaluation of safety and immunogenicity of mRNA-based COVID-19 vaccine (CORNAPCIN) in healthy population: Phase 1 study

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Provides written informed consent prior to initiation of any study procedures Be able to understand the purpose and risks of the study and willing and able to comply with planned study procedures and be available for all study visits Agrees to perform all study procedures, including the collection of venous blood per protocol 18 to 50 years of age, inclusive Body Mass Index 18-35 kg/m² Women of childbearing potential must agree to use a reliable method of contraception from the time of enrollment until sixty days after receiving the intervention and negative urine or serum pregnancy test within 24 hours prior to intervention administration Male subjects of childbearing potential with a female partner of childbearing potential agree to use effective contraception from intervention through 60 days after Male subjects agree to refrain from sperm donation from the time of intervention through 60 days after In good health as determined by medical history and physical examination and the opinion of the principal investigator Has received 3 doses of inactivated Sinopharm or COVIran Barekat vaccine and the time interval from receiving the last dose of vaccine to receiving clinical study intervention at least 90 days and maximum 18 months, vaccination history must be checked and approved through the vaccination record Normal vital signs at the screening visit and at the time of intervention including: temperature less than 38.0 °C; pulse no greater than 100 beats per minute; systolic blood pressure 90 to 140 mmHg and diastolic blood pressure 60 to 90 mmHg; Oxygen saturation ≥ 95%; respiration rate 12 to 20 BPM Clinical screening laboratory evaluations (WBC, Hgb, PLTs, ALT, AST, BUN, Cr, ALP, T.Bili, Lipase, PT, PTT, TSH, T4, FBS, and CRP) are within acceptable normal reference ranges Agree to

refrain from donating blood or plasma during the study (outside of this study)

Exclusion criteria:

Positive pregnancy test either at screening or just prior to intervention administration Female subject who is breastfeeding or plans to breastfeed from the time of intervention through 60 days after Has any medical disease or condition that, in the opinion of the principal investigator, precludes study participation Presence of self-reported or medically documented significant medical (including respiratory, cardiovascular, neurological, autoimmune, Immunodeficiency, and kidney diseases...) or psychiatric condition Has an acute illness within 2 weeks prior to injection, with or without fever [temperature ≥38.0°C], runny nose or eyes, shortness of breath, cough, weakness, and diarrhea, that in the opinion of the principal investigator, precludes study participation Has a positive test result for hepatitis B surface antigen, hepatitis C virus antibody, or HIV types 1 or 2 antibodies Has participated in another investigational study involving any investigational product (study drug, biologic, or device) within 60 days, or 5 half-lives, whichever is longer, before intervention administration Currently enrolled in or plans to participate in another clinical trial during the study period Has previously participated in an investigational study involving lipid nanoparticles (LNPs) Has a history of hypersensitivity or severe allergic reaction (e.g., anaphylaxis, generalized urticaria, angioedema, other significant reaction) to any components of the study product, any previous licensed or investigational vaccines or medication, and to any food or cosmetics History of using any medication that, in the opinion of the principal investigator or the study pharmacist, may be associated with impaired immune responsiveness Anticipating the need for immunosuppressive treatment within Within 6 months after study enrollment Received immunoglobulins and/or any blood or blood products within the 4 months before intervention administration or the possible need to use at any time during the study Has any blood dyscrasias or significant disorder of coagulation Has any chronic liver disease, including fatty liver Has a history of alcohol abuse or other recreational drug use within 6 months before intervention administration Has a positive test result for drugs of abuse at screening Has any abnormality or permanent body art (e.g., tattoo) that would interfere with the ability to observe local reactions at the injection site (deltoid region) Received or plans to receive a licensed, live vaccine within 4 weeks before or after intervention administration Received or plans to receive a licensed, inactivated vaccine within 2 weeks before or after intervention administration History of clinical or virological diagnosis of COVID-19 within 3 months before intervention administration Positive SARS-CoV-2 or influenza PCR test from nasopharyngeal swab at the screening visit, with a maximum time interval of 48 hours between taking the test and intervention administration History of receiving medication to prevent COVID-19 within 3 months before intervention administration On current treatment with investigational agents for prophylaxis of COVID-19 Current use of any

prescription or over-the-counter medications within 7 days prior to intervention administration, unless approved by the investigator or necessary to manage a chronic condition Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection Plan to travel outside Iran from enrollment through 28 days after intervention administration Reside in a nursing home or other skilled nursing facility or have a requirement for skilled nursing care Non-ambulatory Recent (within the last 12 months) use of a dermal filler History of thrombosis Vulnerable groups and foreigners	In this study, the participants' group and the type of intervention they receive will not be disclosed. The site personnel, including the principal investigator, co-investigator, and study team, will be unaware of the type of intervention (CORENAPCIN or placebo) administered to each participant. This is especially important for those who evaluate participants' safety. Vials of vaccine and placebo have the same research label (contains unique blinding codes) and syringes will be relabeled in the same way during intervention preparation so that the person who injects interventions and the participants will not be aware of the type of intervention. An unblinded person is present in the study who holds the randomization list and will assign randomization codes to subjects. This person will not participate in other parts of this clinical study. Randomization information will be stored in opaque sealed envelopes at the study center and in a place with limited access.
Age From 18 years old to 50 years old	Placebo Used
Gender Both	Assignment Parallel
Phase 1	Other design features
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor	In order to identify possible safety signals, vaccination will proceed in a staged fashion. Sentinel groups will be formed with 5 participants (4 subjects injected with CORENAPCIN and 1 subject injected with placebo). Subjects in sentinel groups will stay at the study center and be monitored for 48 hours after the injection. During this period, the injection site will be examined, vital signs and clinical symptoms will be evaluated at specific time intervals, and any adverse event will be documented. Participants in non-sentinel groups will stay at the study center for 2 hours after injection and will be monitored for vital signs and safety events. By comparing the data gathered from safety and immunogenicity assays during the study period, it will be determined which dose will be the right dose of CORENAPCIN to enter the next stages of development.
Sample size Target sample size: 30 Actual sample size reached: 30	Secondary Ids
Randomization (investigator's opinion) Randomized	empty
Randomization description The randomization process in this study will be done in four stages by creating a block randomization sequence (with odd units). In the first block, five participants will randomly be assigned to the sentinel group. Four subjects will receive a dose of 25 micrograms of CORENAPCIN and one subject will receive placebo intervention. In the second phase, after confirming the safety of 25 micrograms of CORENAPCIN in the sentinel group, 10 other participants will randomly be assigned to the study, of whom 8 subjects will receive a dose of 25 micrograms of CORENAPCIN and 2 subjects will receive placebo. For this purpose, two block sequences with size five are generated, including four subjects in the CORENAPCIN group and one subject in the placebo group. In the third phase, five participants will randomly be assigned to the second sentinel group. Four subjects will receive a dose of 50 micrograms of CORENAPCIN and one subject will receive placebo. In the fourth phase, after confirming the safety of 50 micrograms of CORENAPCIN in the sentinel group, 10 other participants will randomly be assigned to the study, of whom 8 subjects will receive a dose of 50 micrograms CORENAPCIN and 2 subjects will receive placebo. For this purpose, two block sequences with size five are generated, including four subjects in the CORENAPCIN group and one subject in the placebo group. Random codes will be generated by R-CRAN software version 4.0.1.	Ethics committees
Blinding (investigator's opinion) Double blinded	1
Blinding description	Ethics committee Name of ethics committee Iran National Committee for Ethics in Biomedical Research Street address Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Sima-ye-Iran St., Qods Town City Tehran Province Tehran Postal code 1467664961

Approval date

2023-01-25, 1401/11/05

Ethics committee reference number

IR.NREC.1401.007

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**

Reactogenicity

Timepoint

During 1 hour after intervention administration

Method of measurement

History checking and examination including injection site examination, clinical and vital signs monitoring, participant reports

2**Description**

Frequency and grade of each solicited local and systemic adverse event

Timepoint

From day 1 (intervention administration) to 7 days after

Method of measurement

History checking and examination including injection site examination, clinical and vital signs monitoring, and participant reports

3**Description**

Frequency and grade of any unsolicited AEs

Timepoint

From day 1 (intervention administration) to 28 days after

Method of measurement

History checking and examination including injection site examination, clinical and vital signs monitoring, participant reports, Clinical laboratory evaluations

4**Description**

Frequency of Serious Adverse Events (SAEs)

Timepoint

from Day 1 (intervention administration) to Day 181

Method of measurement

History checking and examination in follow-up visits, participant reports, Clinical laboratory evaluations

5**Description**

Frequency of New Onset Chronic Medical Conditions (NOCMCs)

Timepoint

from Day 1 (intervention administration) to Day 181

Method of measurement

History checking and examination in follow-up visits, participant reports, Clinical laboratory evaluations

6**Description**

Frequency of Medically Attended Adverse Event (MAAEs)

Timepoint

from Day 1 (intervention administration) to Day 181

Method of measurement

Participant reports

Secondary outcomes**1****Description**

IgG assay to the SARS-CoV-2 S (spike) protein by ELISA method

Timepoint

Days 1, 8, 15, 29, 91, 181

Method of measurement

Geometric mean titer (GMT) of antibody; Percentage of subjects who seroconverted (4-fold increase in antibody titer over baseline); The geometric mean fold rise (GMFR) in IgG titer from baseline

2**Description**

IgG assay to the SARS-CoV-2 receptor-binding domain (RBD) protein by ELISA method

Timepoint

Days 1, 8, 15, 29, 91, 181

Method of measurement

Geometric mean titer (GMT) of antibody; Percentage of subjects who seroconverted (4-fold increase in antibody titer over baseline); The geometric mean fold rise (GMFR) in IgG titer from baseline

3**Description**

Neutralizing antibodies assay (cVNT test)

Timepoint

Days 1 and 15

Method of measurement

Geometric mean titer (GMT) of neutralizing antibody at each timepoint; Percentage of subjects who seroconverted (4-fold increase in antibody titer over baseline); The geometric mean fold rise (GMFR) in neutralizing antibody titer from baseline

4

Description

Evaluation of specific T-cell responses

Timepoint

Days 1 and 15

Method of measurement

Percentage of specific CD4+ and CD8+ lymphocytes producing IFN- γ and IL-4 cytokines measured by flow cytometry

5

Description

Evaluating the response of peripheral blood lymphocytes to vaccination

Timepoint

Days 1, 8, 15, 29.

Method of measurement

Percentage of CD3+, CD4+, CD8+ T cells, B cells and NK cells by Flow cytometry

6

Description

Measurement of serum levels of cytokines IL-10, IL-17, IL-4, IL-2, IL-6, IL-1 β , TNF- α , IFN- γ

Timepoint

Days 1, 8, 15, 29

Method of measurement

ELISA method

Intervention groups

1

Description

Intervention group 1: a single dose of 25 μ g/0.25 ml of CORENAPCIN vaccine (Produced by ReNAP Co.) on day 1, which is received intramuscularly (deltoid muscle). CORENAPCIN is an mRNA vaccine encapsulated by lipid nanoparticles (LNP), containing mRNA encoding the spike protein of the SARS-CoV-2 virus.

Category

Prevention

2

Description

Intervention group 1: a single dose of 50 μ g/0.5 ml of CORENAPCIN vaccine (Produced by ReNAP Co.) on day 1, which is received intramuscularly (deltoid muscle). CORENAPCIN is an mRNA vaccine encapsulated by lipid nanoparticles (LNP), containing mRNA encoding the spike protein of the SARS-CoV-2 virus.

Category

Prevention

3

Description

Control group: single dose of normal saline (0.9% sodium chloride solution for injection), (0.25 or 0.5 ml) on day 1,

which is received intramuscularly (deltoid muscle).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdi clinic

Full name of responsible person

Mohamadreza Salehi

Street address

West side of Imam Khomeini Hospital, East Baqerkhan St., Shahid Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ReNAP Company

Full name of responsible person

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<https://renap.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

ReNAP 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
Pharmed Pajoohan Viera
Full name of responsible person
Maryam Badri
Position
Chief Executive Officer
Latest degree
Master
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available