Study to Evaluate the Safety, Tolerability and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

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Main Information

Primary registry identifying number
LBCTR2020113522

Protocol number
MERS-201

MOH registration number

Study registered at the country of origin
No

Study registered at the country of origin: Specify
A Phase 1 clinical trial evaluating GLS-5300 (which is the same product as INO-4700) has previously been conducted in the United States at Walter Reed Medical Center (clinicaltrials.gov NCT02670187). Additionally, ongoing evaluation in a Phase 1/2a clinical trial is being conducted at two centers in South Korea (clinicaltrials.gov NCT03721718). The MERS-201 clinical trial will not be filed under an Investigational New Drug (IND) application with the United States Food and Drug Administration (FDA). The Middle East and Africa have been selected to advance the MERS -201 clinical trial in a demographically relevant population.

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
28/06/2020

Primary sponsor
Inovio Pharmaceuticals, Inc.

Primary sponsor: Country of origin
USA

Date of registration in primary registry
17/12/2020

Date of registration in national regulatory agency
28/06/2020

Public title
Study to Evaluate the Safety, Tolerability and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

Acronym
MERS-201

Scientific title
Study to Evaluate the Safety, Tolerability and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

Acronym
MERS-201

Brief summary of the study: English
The purpose of this program is to evaluate the safety, tolerability and Immunogenicity of INO-4700 for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) in Healthy Volunteers

Brief summary of the study: Arabic
دراسة لتقييم السلامة ودرجة التحمل والاستمناع لعقار INO-4700 لعلاج فيروس كورونا المرتبط بمتلازمة الشرق الأوسط التنفسية (MERS-CoV) لدى المتطوعين الأصحاء

Health conditions/problem studied: Specify
NA (Healthy Volunteers)

Interventions: Specify

-In Part 1, approximately 192 participants ages 18-50 years will be assessed through five (5) dose levels and regimens. These five (5) dose levels and regimens will be evaluated across nine (9) groups designated Study Groups A, B, C, D, E, F, G, H and I. Study Groups A, B, C, D and E will receive INO-4700 and enroll approximately 32 participants per group. Study Groups F, G, H and I will receive placebo and enroll approximately 8 participants per group. Participants will receive either one or two injections of INO-4700 or Placebo at weeks 0 and 4 or weeks 0 and 8.

Upon completion of the Week 10 visit and availability of immunological data, Part 1 will be unblinded in order to allow for one regimen to be selected for advancement into Part 2. The Study Group with an optimal immune response, an acceptable safety profile and tolerant dosing regimen by Week 10, will be selected for Part 2.

-In Part 2 – Expansion
In Part 2A, participants will be randomized to receive the optimal dose and regimen of active (INO-4700) selected in Part 1 or placebo (SSC-0001). Approximately 300 participants will receive INO-4700 and 50 participants will receive placebo.
In Part 2B, the first 200 participants randomized to the Part 2A Active Study Group will receive a third dose of either INO-4700 or placebo at Week 48.
Similarly, in Part 2B, the first 25 participants randomized to the Part 2A Placebo Study Group will receive a third dose of placebo at Week 48.

-Dosage Regimen:
 Part 1 Group A – One 0.6 mg ID injection of INO-4700 followed by EP administered at Day 0 and Week 4 (± 5 days)
 Part 1 Group B – One 1.0 mg ID injection of INO-4700 followed by EP administered at Day 0 and Week 4 (± 5 days)
 Part 1 Group C – One 1.0 mg ID injection of INO-4700 followed by EP administered at Day 0 and Week 8 (± 5 days)
 Part 1 Group D – Two 0.5 mg ID injections (in an acceptable location on two different limbs) of INO-4700 followed by EP administered at Day 0 and Week 8 (± 5 days)
 Part 1 Group E – Two 1.0 mg ID injections (in an acceptable location on two different limbs) of INO-4700 followed by EP administered at Day 0 and Week 4 (± 5 days)
 Part 1 Group F – One ID injection of placebo followed by EP administered at Day 0 and Week 4 (± 5 days)
 Part 1 Group G – One ID injection of placebo followed by EP administered at Day 0 and Week 8 (± 5 days)
 Part 1 Group H – Two ID injections (in an acceptable location on two different limbs) of placebo followed by EP administered at Day 0 and Week 8 (± 5 days)
 Part 1 Group I – Two ID injections (in an acceptable location on two different limbs) of placebo followed by EP administered at Day 0 and Week 4 (± 5 days)
 Part 2 – Dose and regimen to be determined, each ID injection(s) followed by EP administered at Day 0, Week 4 or Week 8, and Week 48 (for Part 2B participants receiving a third dose)

-After each injection, the CELLECTRA (TM) 2000 device will be used to enhance the uptake and expression of the DNA plasmid (INO-4700) in order to enhance vaccine immunogenicity.

Key inclusion and exclusion criteria: Inclusion criteria

a. Able to provide informed consent and have signed Informed Consent Form (ICF) prior to screening procedures;
b. For Part 1, adults age 18 and 50 years, inclusive. For Part 2, adults at least 18 years of age;
c. Judged to be healthy by the Investigator on the basis of medical history, physical examination and vital signs performed at Screening. Note: Participants taking daily prescription or non-prescription medications for management of acceptable chronic medical conditions must be on a stable dose, as defined by non-change in dose for the 3 months prior to the first dose of study medication and no planned changes during the active dosing period of the study;
d. Able and willing to comply with all study procedures;
e. Screening laboratory results within normal limits for testing laboratory or deemed not clinically significant by the Investigator;
f. Negative serological tests for Hepatitis B surface antigen (HBsAg), Hepatitis C antibody and Human Immunodeficiency Virus (HIV) antibody or rapid test at screening;
g. Screening ECG deemed by the Investigator as having no clinically significant findings (e.g. Wolff-Parkinson-White syndrome);
h. Must meet one of the following criteria with respect to reproductive capacity:
 Women who are post-menopausal as defined by spontaneous amenorrhea for ≥ 12 months;
 Surgically sterile or have a partner who is sterile (i.e., vasectomy in males at least six (6) months prior to enrollment or tubal ligation, absence of ovaries and/or uterus in females);
 Use of medically effective contraception with a failure rate of < 1% per year when used consistently and correctly from screening until 1 month following

last dose.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

100

Key inclusion and exclusion criteria: Exclusion criteria

a. Pregnant or breastfeeding, or intending to become pregnant or father children within the projected duration of the trial starting with the screening visit until 1 month following last dose;
b. Positive serum pregnancy test during screening or positive urine pregnancy test prior to dosing;
c. History of respiratory diseases such as asthma, chronic obstructive pulmonary disease or chronic bronchitis;
d. Is currently participating in or has participated in a study with an investigational product with 30 days preceding Day 0;
e. Previous receipt of an investigational vaccine product for prevention of MERS or SARS;
f. Prior exposure to MERS-CoV or camels (serology or antibody testing will be requested at the Investigator's discretion);
g. Participants who participated in MERS-201 Part 1 cannot participate in MERS-201 Part 2;
h. Fewer than two acceptable sites available for ID injection and EP considering the deltoid and anterolateral quadriceps muscles. The following are unacceptable sites:
 Tattoos, keloids or hypertrophic scars located within 2 cm of intended administration site;
 Implantable-Cardioverter-defibrillator (ICD) or pacemaker (to prevent a lifethreatening arrhythmia) that is located ipsilateral to the deltoid injection site (unless deemed acceptable by a cardiologist);
 Any metal implants or implantable medical device within the electroporation site;
i. Prisoner or participants who are compulsorily detained (involuntary incarceration);
j. Current or anticipated concomitant immunosuppressive therapy (excluding inhaled, topical skin and/or eye drop-containing corticosteroids) prior to dosing. Systemic corticosteroids must be discontinued at least 3 months prior to first dose;
k. Reported active drug or alcohol or substance abuse or dependence.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Other

Trial scope: Specify scope

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

Study phase

2

Study design: Purpose

Prevention

Study design: Specify purpose

N/A

Study design: Assignment

Parallel

Study design: Specify assignment

N/A

IMP has market authorization

No

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

INO-4700

Type of IMP

Others

Pharmaceutical class

DNA Vaccines followed Electroporation (CELLECTRA (TM) 2000)

Therapeutic indication

Middle East Respiratory Syndrome Coronavirus (MERS-CoV)

Therapeutic benefit

There may be potential benefit for prevention of MERS infection in affected areas.
The CELLECTRATM 2000 device is indicated to enhance the uptake and expression of DNA plasmid-based biologics in order to enhance vaccine immunogenicity.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Biospecimen description

Whole blood and serum samples will be obtained to assess overall immune response.
Details of the immunology sample collection and shipment information will be provided in the Laboratory Manual. The T and B cell immune responses to INO-4700 will be measured using assays that include but are not limited to ELISA, neutralization, assessment of immunological gene expression, assessment of immunological protein expression, flow cytometry and ELISPOT.

Target sample size

542

Actual enrollment target size

542

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

19/10/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

31/10/2023

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

Yes

IPD sharing statement description

Data dictionaries and all collected IPD will be stripped of identifiers and may be made available upon request. Supporting Information includes the Study Protocol and Informed Consent Form (ICF). Anonymous IPD may be shared following or during the publication of summary data. Archival data may be accessed for up to 10 years following the end of the study.

Those who request the anonymous IPD must provide a plan of study explaining how the data will be used. Requests may be sent to the Central Contact Person. Requests will be reviewed based on the potential for the planned use of the IPD for advancing scientific knowledge and theory.

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
NA	NA

Sources of Monetary or Material Support

Name
Inovio Pharmaceuticals, Inc.
Coalition for Epidemic Preparedness Innovations (CEPI)

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Aziz Zoghbi	MCT-CRO, Berytech Technology and Health, 5th Floor Damascus Road, Beirut, Lebanon	Lebanon	+9611612 500	zog_az@mct-cro.com	Director of Country Oversight and Management Africa, Levant and GCC
Scientific	Mammen Mammen	US, Plymouth Meeting	United States of America	001 301-305-4487	mammen.mammen@inovio.com	Senior Vice President, Clinical Development
Public	Inovio Call Center N/A	NA	United States of America	001 (267) 440-4237	clinical.trials@inovio.com	Inovio call Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Dr. Georges Fhaily	Emergency Doctor	Approved
American University of Beirut Medical Center	Dr. Zeina Kanafani	Infectious Disease	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	22/09/2020	Mrs. Ghada Aoun	medical@hammoudhospital.org	00961 7 721021
American University of Beirut Medical Center	23/11/2020	Ms. Abir Dakik	ad17@aub.edu.lb	00961 1 340460

Countries of Recruitment

Name
Lebanon
Jordan
Saudi Arabia
Kenya

Health Conditions or Problems Studied

Condition	Code	Keyword
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Vaccine or biological substance, unspecified (Y59.9)	Healthy Coronavirus

Interventions

Intervention	Description	Keyword
INO-4700	Experimental: Part 1: INO-4700 Group A Participants will receive one ID injection of 0.6 milligram (mg) of INO-4700 followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 4	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
INO-4700	Experimental: Part 1: INO-4700 Group B Participants will receive one ID injection of 1.0 mg of INO-4700 followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 4.	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
INO-4700	Experimental: Part 1: INO-4700 Group C Participants will receive one ID injection of 1.0 mg of INO-4700 followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 8.	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
INO-4700	Experimental: Part 1: INO-4700 Group D Participants will receive two ID injections (in an acceptable location on two different limbs) of 0.5 mg each of INO-4700 followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 8.	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
INO-4700	Experimental: Part 1: INO-4700 Group E Participants will receive two ID injections (in an acceptable location on two different limbs) of 1.0 mg each of INO-4700 followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 4.	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
Placebo (SSC-0001) Sterile saline sodium citrate buffer	Placebo Comparator: Part 1: Placebo Group F Participants will receive one ID injection of placebo followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 4.	Drug: Placebo Sterile saline sodium citrate (SSC) buffer (SSC-0001) will be administered ID. Other Names: • SSC-0001 Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
Placebo (SSC-0001) Sterile saline sodium citrate buffer	Placebo Comparator: Part 1: Placebo Group G Participants will receive one ID injection of placebo followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 8.	Drug: Placebo Sterile saline sodium citrate (SSC) buffer (SSC-0001) will be administered ID. Other Names: • SSC-0001 Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
Placebo (SSC-0001) Sterile saline sodium citrate buffer	Placebo Comparator: Part 1: Placebo Group H Participants will receive two ID injections (in an acceptable location on two different limbs) of placebo followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 8.	Drug: Placebo Sterile saline sodium citrate (SSC) buffer (SSC-0001) will be administered ID. Other Names: • SSC-0001 Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
Placebo (SSC-0001) Sterile saline sodium citrate buffer	Placebo Comparator: Part 1: Placebo Group I Participants will receive two ID injections (in an acceptable location on two different limbs) of placebo followed by EP using the CELLECTRA™ 2000 device on Day 0 and Week 4.	Drug: Placebo Sterile saline sodium citrate (SSC) buffer (SSC-0001) will be administered ID. Other Names: • SSC-0001 Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration
INO-4700	Experimental: Part 2: Parts 2A and 2B Participants will receive ID injection of INO-4700 based on optimal dose and regimen selection in Part 1 followed by EP using the CELLECTRA™ 2000 device on Day 0, Week 4 or Week 8 and a booster dose at Week 48 (only for Part 2B participants receiving a third dose)	Drug: INO-4700 INO-4700 will be administered ID. Device: CELLECTRA™ 2000 EP using the CELLECTRA™ 2000 device will be administered following ID drug administration

Primary Outcomes

Name	Time Points	Measure
Tolerability and safety of INO-4700 administered by ID injection	Duration of both parts 1 (up to week 48) and 2 (up to week 68) of the study	Incidence of Adverse Events, Number and severity of injection site reactions, Incidence of Adverse Events of Special Interest
Cellular (T Cell) and Humoral immune response to INO-4700 administered by ID injection to select the optimal dose and regimen	Part 1: Week 10.	MERS-CoV antigen specific antibodies, Antigen specific cytokine producing T cell responses
Safety and immunogenicity of selected optimal dose	Part 2: up to week 68	MERS-CoV antigen specific antibodies, Antigen specific cytokine producing T cell responses, Incidence of Adverse Events, Number and severity of injection site reactions, Incidence of Adverse Events of Special Interest

Key Secondary Outcomes

Name	Time Points	Measure
NA	NA	NA

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files