Footnote 12

A Phase II Clinical Trial to Evaluate the Recombinant Vaccine for COVID-19 (Adenovirus Vector) (CTII-nCoV)

ClinicalTrials.gov Identifier: NCT04341389

Recruitment Status : Active, not recruiting
First Posted : April 10, 2020
Last Update Posted : May 18, 2020

Sponsor:
Insitute of Biotechnology, Academy of Military Medical Sciences, PLA of China

Collaborators:
CanSino Biologics Inc.
Jiangsu Province Centers for Disease Control and Prevention
Hubei Provincial Center for Disease Control and Prevention
Zhongnan Hospital

Information provided by (Responsible Party):
Insitute of Biotechnology, Academy of Military Medical Sciences, PLA of China

Study Description

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Brief Summary:

This is a phase II, randomised, double-blinded and placebo-controlled clinical trial in healthy adults above 18 years of age. This clinical trial is designed to evaluate the immunogenicity and safety of **Ad5-nCoV** which encodes for a full-length spike (S) protein of SARS-CoV-2.

Condition or disease	Intervention/treatment	Phase
COVID-19	Biological: Recombinant novel coronavirus vaccine (Adenovirus type 5 vector) Other: Placebo	Phase 2

Detailed Description:

This is a phase II, randomised, double-blinded and placebo-controlled clinical trial in healthy adults above 18 years of age,inclusive, who meet all eligibility criteria. This clinical trial is designed to evaluate the immunogenicity and safety of Ad5-nCoV which encodes for a full-length spike (S) protein of SARS-CoV-2. 500 subjects will be enrolled, 250 subjects in middle-dose vaccine group, 125 subjects in low-dose and placebo group, respectively. Immunogenicity will be tested on days 0, 14, 28 and 6 months after vaccination

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

508 participants

Allocation:

Randomized

Intervention Model:

Crossover Assignment

Masking:

Double (Participant, Investigator)

Primary Purpose:

Prevention

Official Title:

A Randomized, Double-blind, Placebo-controlled Phase II Clinical Trial to Evaluate the Safety and Immunogenicity of the Recombinant Novel Coronavirus Vaccine (Adenovirus Vector) in Healthy Adults Aged Above 18 Years

Actual Study Start Date :

April 12, 2020

Estimated Primary Completion Date :

January 31, 2021

Estimated Study Completion Date :

January 31, 2021

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Arm 1 1×10^11vp of **Ad5-nCoV** administered through 1.0 mL intramuscular injection in the deltoid muscle on Day 0	Biological: Recombinant novel coronavirus vaccine (Adenovirus type 5 vector) Intramuscular injection Other Name: **Ad5-nCoV**
Active Comparator: Arm 2 5×10^10vp of **Ad5-nCoV** administered through 1.0 mL intramuscular injection in the deltoid muscle on Day 0	Biological: Recombinant novel coronavirus vaccine (Adenovirus type 5 vector) Intramuscular injection Other Name: **Ad5-nCoV**
Placebo Comparator: Arm 3 Placebo administered through 1.0 mL intramuscular injection in the deltoid muscle on Day 0	Other: Placebo Intramuscular injection Other Name: Control

Outcome Measures

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Primary Outcome Measures :

1. Occurrence of adverse reactions [Time Frame: 0-14 days post vaccination]
2. Anti SARS-CoV-2 S IgG antibody response(ELISA) [Time Frame: 28 days post vaccination]
3. Neutralizing antibody response to SARS-CoV-2 [Time Frame: 28 days post vaccination]

Secondary Outcome Measures :

1. Occurrence of adverse events [Time Frame: 0-28 days post vaccination]
2. Occurrence of serious adverse reaction [Time Frame: 0-6 months post vaccination]

3. Anti SARS-CoV-2 S IgG antibody response(ELISA) [Time Frame: 0, 14 days and 6 months post vaccination]
4. Neutralizing antibody response to SARS-CoV-2 [Time Frame: 0 and 6 months post vaccination]
5. Neutralizing antibody response to Ad5-vector [Time Frame: 0, 28 days and 6 months post vaccination]
6. IFN-γ ELISpot responses to SARS-CoV-2 spike protein [Time Frame: 0 and 28 days post vaccination]

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Aged between 18 and 60 years.
- Able to understand the content of informed consent and willing to sign the informed consent
- Able and willing to complete all the secluded study process during the whole 6 months study follow-up period.
- Negative in HIV diagnostic test.
- Negative in serum antibodies (IgG and IgM) screening of COVID-19.
- Axillary temperature ≤37.0°C.
- The BMI index is 18.5-30.0.

- General good health as established by medical history and physical examination.

Exclusion Criteria:

- Family history of seizure, epilepsy, brain or mental disease
- Subject allergic to any component of the investigational vaccine, or a more severe allergic reaction and history of allergies in the past.
- Woman who is pregnant, breast-feeding or positive in β-HCG (human chorionic gonadotropin) pregnancy test (urine) on day of enrollment, or become pregnant during the next 6 months
- Any acute fever disease or infections.
- History of SARS
- Major congenital defects or not well-controlled chronic illness, such as asthma, diabetes, or thyroid disease.
- Serious cardiovascular diseases, such as arrhythmia, conduction block, myocardial infarction, severe hypertension without controllable drugs, etc.
- Hereditary angioneurotic edema or acquired angioneurotic edema
- Urticaria in last one year
- No spleen or functional spleen.
- Platelet disorder or other bleeding disorder may cause injection contraindication
- Faint at the sight of needles.
- Prior administration of immunodepressant or corticosteroids, antianaphylaxis treatment, cytotoxic treatment in last 6 months.
- Prior administration of blood products in last 4 months
- Prior administration of other research medicines in last 1 month
- Prior administration of attenuated vaccine in last 1 month
- Prior administration of inactivated vaccine in last 14 days
- Current anti-tuberculosis prophylaxis or therapy
- According to the judgement of investigator,various medical, psychological, social or other conditions, those could affect the subjects to sign informed consent.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04341389***

Locations

China, Hubei

Hubei Provincial Center for Disease Control and Prevention
Wuhan, Hubei, China

Sponsors and Collaborators

Insitute of Biotechnology, Academy of Military Medical Sciences, PLA of China

CanSino Biologics Inc.

Jiangsu Province Centers for Disease Control and Prevention

Hubei Provincial Center for Disease Control and Prevention

Zhongnan Hospital

Investigators

Principal Investigator: Fengcai Zhu, MD Jiangsu Province Centers of Disease Control and Prevention

More Information

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Responsible Party:
Insitute of Biotechnology, Academy of Military Medical Sciences, PLA of China

ClinicalTrials.gov Identifier:
NCT04341389 History of Changes

Other Study ID Numbers:
JSVCT089

First Posted:
April 10, 2020 Key Record Dates

Last Update Posted:
May 18, 2020

Last Verified:
May 2020

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Keywords provided by Insitute of Biotechnology, Academy of Military Medical Sciences, PLA of China:

COVID-19 vaccine

Ad5-nCoV

SARS-CoV-2

Additional relevant MeSH terms:

Adenoviridae Infections

DNA Virus Infections

Virus Diseases

Safety and Immunogenicity Study of Inactivated Vaccine for Prevention of SARS-CoV-2 Infection(COVID-19)

ClinicalTrials.gov Identifier: NCT04383574

Recruitment Status : Not yet recruiting
First Posted : May 12, 2020
Last Update Posted : May 12, 2020

See **Contacts and Locations**

Sponsor:
Sinovac Research and Development Co., Ltd.

Information provided by (Responsible Party):
Sinovac Biotech Co., Ltd (**Sinovac** Research and Development Co., Ltd.)

Study Description

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Brief Summary:
This study is a randomized, double-blinded, and placebo controlled phase 1&2 clinical trial of the SARS-CoV-2 inactivated vaccine manufactured by **Sinovac** Research & Development Co., Ltd. The purpose of this study is to evaluate the safety and immunogenicity of the experimental vaccine in healthy adults aged≥60 years.

Condition or disease	Intervention/treatment	Phase
COVID-19	Biological: Two doses of low dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 Biological: Two doses of medium dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 Biological: Two doses of high dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 Other: Two doses of placebo at the schedule of day 0,28	Phase 1 Phase 2

Detailed Description:
This study is a randomized, double-blinded, single-center, placebo-controlled phase 1&2 clinical trial in adults aged≥60 years. The experimental vaccine and placebo were both manufactured by Sinovac Research & Development Co., Ltd. A total of 422 subjects will be enrolled, with 72 at phase 1, and 350 at phase 2. Subjects will be assigned to receive two doses of different dosage of experimental vaccine or placebo on the schedule of day 0,28.

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
422 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Double (Participant, Investigator)

Primary Purpose:
Prevention

Official Title:
A Randomized, Double-Blinded, Placebo-Controlled, Phase I/II Clinical Trial, to Evaluate the Safety and Immunogenicity of the SARS-CoV-2 Inactivated Vaccine (Vero Cell) in Healthy Population Aged ≥60 Years

Estimated Study Start Date :

May 20, 2020

Estimated Primary Completion Date :

July 20, 2020

Estimated Study Completion Date :

July 20, 2020

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Experimental Vaccine-low dosage low dosage inactivated SARS-CoV-2 vaccine	Biological: Two doses of low dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 The inactivated SARS-CoV-2 vaccine was manufactured by **Sinovac** Research & Development Co., Ltd., with a antigen content of 300SU/ml
Experimental: Experimental Vaccine-medium dosage medium dosage inactivated SARS-CoV-2 vaccine	Biological: Two doses of medium dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 The inactivated SARS-CoV-2 vaccine was manufactured by **Sinovac** Research & Development Co., Ltd., with a antigen content of 600SU/ml
Experimental: Experimental Vaccine-high dosage high dosage inactivated SARS-CoV-2 vaccine	Biological: Two doses of high dosage inactivated SARS-CoV-2 vaccine at the schedule of day 0,28 The inactivated SARS-CoV-2 vaccine was manufactured by **Sinovac** Research & Development Co., Ltd., with a antigen content of 1200SU/ml
Placebo Comparator: Placebo No active ingredient in the placebo	Other: Two doses of placebo at the schedule of day 0,28 The placebo contains no active ingredient and manufactured by **Sinovac** Research & Development Co., Ltd.

Outcome Measures

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Primary Outcome Measures :

1. Safety index-incidence of adverse reactions [Time Frame: Day 0-28 after each dose vaccination]

   Incidence of adverse reactions after each dose vaccination

2. Immunogenicity index-seroconversion rates of neutralizing antibody [Time Frame: The 30th day after the second dose vaccination]

   Neutralizing antibody assay will be performed using the micro-neutralization method. Seroconversion will be defined as a change from seronegative (<1:8) to seropositive (≥1:8), or ≥4 fold increase from baseline.

Secondary Outcome Measures :

1. Safety index-incidence of serious adverse events [Time Frame: From the beginning of the vaccination to 12 months after the second dose vaccination]

   SAE will be collected throughout the clinical trial

2. Immunogenicity index-seropositive rates of neutralizing antibody [Time Frame: The 30th day and the 12 month after the second dose vaccination]

   Neutralizing antibody assay will be performed using the micro-neutralization method, and subjects with a antibody titer ≥1:8 will defined as seropositive.

3. Immunogenicity index-geometric mean titer (GMT) of neutralizing antibody [Time Frame: The 30th day and the 12 month after the second dose vaccination]

   Neutralizing antibody assay will be performed using the micro-neutralization method

4. Immunogenicity index-geometric mean ratio (GMR) of neutralizing antibody [Time Frame: The 30th day after the second dose vaccination]

   Neutralizing antibody assay will be performed using the micro-neutralization method. Ratio of post-vaccination titer divided by baseline titer will be calculated.

Eligibility Criteria

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Information from the National Library of Medicine

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Ages Eligible for Study:

60 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Healthy adults aged ≥60 years;
- Proven legal identity;
- Participants should be capable of understanding the informed consent form, and such form should be signed prior to enrolment ;

Exclusion Criteria:

- Travel history / residence history of Wuhan city and surrounding areas, or other communities with case reports within 14 days;
- History of contact with a SARS-CoV-2 infection (positive in nucleic acid test) within 14 days;
- Have contacted patients with fever or respiratory symptoms from Wuhan and surrounding areas, or from communities with case reports within 14 days;
- Two or more cases of fever and / or respiratory symptoms in a small contact area of volunteers, such as home, office etc. within 14 days;
- History of SARS-CoV-2 infection;
- History of asthma, history of allergy to the vaccine or vaccine components, or serious adverse reactions to the vaccine, such as urticaria, dyspnea, and angioedema;
- Congenital malformations or developmental disorders, genetic defects, severe malnutrition, etc.;

- Autoimmune disease or immunodeficiency / immunosuppression;
- Severe chronic diseases, severe cardiovascular diseases, hypertension and diabetes that cannot be controlled by drugs, liver or kidney diseases, malignant tumors, etc.;
- Severe neurological disease (epilepsy, convulsions or convulsions) or mental illness;
- Thyroid disease or history of thyroidectomy, spleenlessness, functional spleenlessness, spleenlessness or splenectomy resulting from any condition;
- Diagnosed abnormal blood coagulation function (eg, lack of blood coagulation factors, blood coagulopathy, abnormal platelets) or obvious bruising or blood coagulation;
- Immunosuppressive therapy, cytotoxic therapy, inhaled corticosteroids (excluding allergic rhinitis corticosteroid spray therapy, acute noncomplicated dermatitis superficial corticosteroid therapy) in the past 6 months;
- History of alcohol or drug abuse;
- Receipt of blood products within in the past 3 months;
- Receipt of other investigational drugs in the past 30 days;
- Receipt of attenuated live vaccines in the past 14 days;
- Receipt of inactivated or subunit vaccines in the past 7 days;
- Acute diseases or acute exacerbation of chronic diseases in the past 7 days;
- Axillary temperature >37.0°C;
- According to the investigator's judgment, the subject has any other factors that are not suitable for participating in the clinical trial

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04383574***

Contacts

Contact: Yuliang Zhao, Master 86-13315290538 yuliang_zh@163.com

Locations

China, Hebei

Renqiu City Center for Disease Control and Prevention
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Contact: Hui Jin 86-13930778699 1206618652@qq.com

Sponsors and Collaborators

Sinovac Research and Development Co., Ltd.

Investigators

Principal Investigator: Yuliang Zhao, Master Hubei Provincial Center for Disease Control and Prevention

More Information

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Responsible Party:

Sinovac Research and Development Co., Ltd.

ClinicalTrials.gov Identifier:

NCT04383574 History of Changes

Other Study ID Numbers:

PRO-nCOV-1002

First Posted:

May 12, 2020 Key Record Dates

Last Update Posted:

May 12, 2020

Last Verified:

May 2020

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Vaccines
Immunologic Factors
Physiological Effects of Drugs