Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

Safety and immunogenicity of SARS-CoV-2 inactivated vaccine (OSVID-19) in healthy volunteers aged 18 to 40 years: A clinical trial, phase 1, single arm

Protocol summary

Study aim

Safety and immunogenicity of the inactivated vaccine Osvid-19 at a dose of 0.5 ml and 28 days within two intramuscular injections in a healthy population of 18 to 40 years

Design

Phase I clinical trial, single arm without blinding and randomization with a sample size of 40 healthy volunteers aged 18 to 40 years

Settings and conduct

The study will be performed on 40 healthy volunteers aged 18 to 40 years at the site provided by Osve Pharmaceutical Company. After screening the volunteers and confirming their eligibility to recruit to the study, Osvid-19 vaccine candidate is injected in 0.5 ml dose twice on days 0 and 28, and safety and immunogenicity is followed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Healthy volunteer 18 to 40 years, both sexes, written informed consent; without any uncontrolled underlying disease; Appropriate general health and mental health; not to participate in another clinical trial for the duration of the study; Exclusion criteria: Documented history of Covid-19 infection; History of covid-19 vaccine/ vaccine candidate Injection ; Unacceptable laboratory finding/ abnormalities at screening; temperature more than 37 C; For women, positive pregnancy serum test

Intervention groups

Two dose of 5 micrograms Osivd-19 vaccine candidate with an interval of 4 weeks

Main outcome variables

incidence of immediately reaction after injection of the vaccine, local reactions at the injection site, systemic reactions seven days after injection (including fever, headache, chills, nausea, vomiting, diarrhea, muscle pain in the joints, etc.), incidence of any Serious / non-serious adverse event during follow-up, abnormal results of laboratory findings, IgM and IgG antibody titers, evaluation of neutralizing antibody activity, cytokines evaluation: interleukins 2, 4, 5 and 6, IFN-γ, TNF-α, incidence And severity of symptomatic and asymptomatic SARS-COV-2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210622051670N1**
Registration date: **2021-12-30, 1400/10/09**
Registration timing: **prospective**

Last update: **2021-12-30, 1400/10/09**
Update count: **0**

Registration date

2021-12-30, 1400/10/09

Registrant information

Name

Ali Asghar Akhlaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 0487

Email address

ceo@cellechco.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and immunogenicity of SARS-CoV-2 inactivated vaccine (OSVID-19) in healthy volunteers aged 18 to 40 years: A clinical trial, phase 1, single arm

Public title

Phase I clinical trial of Osvid-19 inactivated vaccine for Covid-19 (Osve Pharmaceutical Company)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteers between the ages of 18 and 40 of both sexes; Ability to provide informed written consent; Volunteers who are healthy and do not have any uncontrolled underlying disease; Appropriate general health and mental health as determined by the principal investigator (including: normal vital signs, heart rate between 60 and 100 (beat/ min); systolic blood pressure ≥90 mm Hg and <140 mm; Diastolic blood pressure ≥ 60 mm Hg and <90 mm Hg; oral temperature less than 37.3 ° C (temperature less than 0.37 ° C digitally), physical examination and review of medical records); Expressing interest and availability to conduct studies and visits; For female participants of childbearing age, ensuring no plan for pregnancy / using a reliable method of contraception and not planning for pregnancy at least from the time of enrollment to 4 weeks after the second dose of vaccine; Males use a safe method of prevention such as condoms at least three months after the second dose of vaccination; The male volunteer agrees not to donate sperm for three months after the second vaccine; volunteers should refrain from donating blood or plasma from the recruitment until three months after the second dose of the vaccine; Volunteers agree not to participate in another clinical trial for the duration of the study; The volunteer agrees to stay in the study area for the entire duration of the study.

Exclusion criteria:

Documented history of Covid-19 infection (principal investigator determines the final summary of the volunteer's history of infection by examining the set of clinical symptoms related to Covid-19 include: positive PCR test, pulmonary involvement documents, family members' history); History of participation in studies of other Covid-19 vaccines candidates; History of Covid-19 vaccine injection; Unacceptable laboratory abnormalities from screening (before the first vaccination), or immune assay, as follows: [Abnormal blood parameters (CBC), random blood sugar level, renal function, test (serum urea and creatinine)), Liver function tests, urinalysis reports, or patients with a specific history of HIV infection; for women, positive pregnancy serum test (during screening within 45 days of enrollment); Temperatures above 37 ° C by digital thermometry and temperatures above 37.3 ° C by oral thermometry (in suspected cases) or symptoms such as upper respiratory tract infection or gastritis within three days before each Vaccine dose; Medical problems as a result of alcohol or drug use over the past 12 months.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

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

National Research Ethics Committee

Street address

13th floor, Block A, Ministry of health, Simaye Iran street, Shahrake ghods(qarb)

City

Tehran

Province

Tehran

Postal code

1417993337

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR.NREC.1400.011

Health conditions studied

1

Description of health condition studied

COVID-19 disease

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description
immediate reaction after injection
Timepoint
0-3 hours after injection
Method of measurement
Close observation/ monitoring

2

Description
Local reactions at the injection site
Timepoint
0-7 days after injection
Method of measurement
Close observation/ monitoring

3

Description
Systemic reactions
Timepoint
0-7 days after injection
Method of measurement
Close observation/ monitoring

4

Description
Abnormal results of laboratory findings
Timepoint
Baseline and 2 weeks after inejection
Method of measurement
Blood and urine sampling, lab tests

5

Description
Incidence of any adverse event (serious or non-serious)
Timepoint
0, 2 weeks, 4 weeks ,6 weeks, 3, 6 and 12 months
Method of measurement
Examination, history, and report of the study participant/ Medical dictionary

6

Description
Neutralizing Antibody titer/ activity
Timepoint
0, 2 weeks, 4 weeks, 6 weeks, 3, 6 and 12 months
Method of measurement
ELISA

Secondary outcomes

1

Description
Cytokines; IL2, IL4, IL5 and IL6, IFN-γ, TNF-α
Timepoint
Baseline, 4 weeks, 6 weeks
Method of measurement
ELISA

2

Description
Incidence and severity of symptomatic and asymptomatic SARS-COV-2
Timepoint
Baseline, 4 weeks, 6 weeks, 3 months, 6 months, 12 months
Method of measurement
PCR, severity grading

3

Description
Seroconversion
Timepoint
Baseline, 4 weeks, 6 weeks, 3 months, 6 months, 12 months
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: COVID-19 vaccine candidate; two dose of 5 micrograms with an interval of 4 weeks; Intramuscular injection (deltoid muscle)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Osve pharmaceutical company recruitment site
Full name of responsible person
Dr Morteza Izadi
Street address
No. 35, West Saeb Tabrizi St., Sheikh Bahaei St.,
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Tehran
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Postal code
1993625361
Phone
+98 21 8803 3160
Email
biotechmng@osvahpharma.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Osve pharmaceutical company
Full name of responsible person
Dr Mahdi Bakhshayesh
Street address
17 Shahrivar street, Shad Abad, before Pasteurized milk intersection, km 4 of Karaj old road, Tehran
City
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Postal code
1371845311
Phone
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Email
info@osvahpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Osve pharmaceutical 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
Osve pharmaceutical company
Full name of responsible person
Dr Negar Mohseni
Position
Pharm D
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
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Ozone Therapy Center (First Floor); No.2; Azam alley; Sheikh Baha'i St. South; Mulla Sadra St.; Vanak Square
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Person responsible for updating data

Contact
Name of organization / entity
Zistfan Daru Donyan company
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Methodologist
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Ph.D.
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Biostatistics
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akhlaghi90@gmail.com

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