

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

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 Osvid-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 injection

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.,

City

Tehran

Province

Tehran

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

Tehran

Province

Tehran

Postal code

1371845311

Phone

+98 21 6680 1075

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

Street address

17 Shahrivar St., before Pasteurized Milk Three Ways, Shad Abad, 4 km of Karaj Old Road, Tehran

City

Tehran

Province

Tehran

Postal code

1371849311

Phone

+98 21 8803 9036

Email

biotechmng@osvahpharma.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr Morteza Izadi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Ozone Therapy Center (First Floor); No.2; Azam alley; Sheikh Baha'i St. South; Mulla Sadra St.; Vanak Square

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8804 6515

Email

Morteza_izadi@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Zistfan Daru Donyan company

Full name of responsible person

Ali Asghar Akhlaghi

Position

Methodologist

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

Street address

Unit 2, No. 12, Arab Najafi Alley, Tehran Villa Three Ways, Sattar Khan St.

City

Tehran

Province

Tehran

Postal code

123

Phone

+98 21 6653 0487

Email

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