

# 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 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- $\gamma$ , TNF- $\alpha$ , 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  $\geq 90$  mm Hg and  $< 140$  mm; Diastolic blood pressure  $\geq 60$  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- $\gamma$ , TNF- $\alpha$

#### **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