

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Dec 2023

Short-term Protection for COVID-19 by Oral Polio Vaccine

Protocol summary

Study aim

To assess if OPV can be used as a short-term preventive measure in human against SARS-CoV-2.

Design

Non-randomized non-blinded parallel design clinical trial on 130,000 people

Settings and conduct

Within 1 month, all people who receive health care services from Fars, Hormozgan and Ahwaz PIHO will be called upon to participate in this study. They will be given 4 drops of OPV by a medic after granting informed consents. No randomization or blinding used.

Participants/Inclusion and exclusion criteria

Population: All people receiving health care services from PIHO residing in Fars, Hormozgan, and Ahwaz centers.
Inclusion Criteria: All people receiving health care services from PIHO in the three provinces who agree to participate in the study. Exclusion Criteria: Contraindication for receiving OPV.

Intervention groups

Single shot of OPV vaccination given to the eligible people

Main outcome variables

Adjusted Incidence (Risk) Ratio of COVID-19

General information

Reason for update

Acronym

COP

IRCT registration information

IRCT registration number: **IRCT20140428017469N1**
Registration date: **2020-05-23, 1399/03/03**
Registration timing: **prospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Farrokh Habibzadeh

Name of organization / entity

The IJOEM

Country

Iran (Islamic Republic of)

Phone

+98 71 1225 2258

Email address

farrokh.habibzadeh@theijoem.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-13, 1399/03/24

Expected recruitment end date

2020-07-14, 1399/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short-term Protection for COVID-19 by Oral Polio Vaccine

Public title

Polio Vaccine and COVID-19

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All people receiving health care services from PIHO in the three provinces who agree to participate in the study (Fars, Hormozgan and Khuzestan).

Exclusion criteria:

All those with contraindication to receive OPV including immunocompromised people and those living with an immunocompromised person (including those with active

malignancy receiving chemo/radiation therapy, transplant recipients receiving immunosuppressant drugs, those with active HIV infection, and those with congenital immunodeficiency). Those with severe flu, high-grade fever, and history of allergy to other vaccines will be excluded too. We will also exclude those who have newborn children who may be yet unimmunized against polio.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **130000**

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**

IR.SUMS.REC.1399.183

Street address

R&D Headquarters, PIHO, Eram Blvd, Shiraz
71438-37877, Iran

City

Shiraz

Province

Fars

Postal code

7143837877

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.SUMS.REC.1399.183

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

covid-19, virus identified

Primary outcomes**1****Description**

The age-adjusted incidence of COVID-19 in vaccinated people compared with that in unvaccinated general population (aRR).

Timepoint

2 months after vaccination

Method of measurement

daily count of new patients

Secondary outcomes**1****Description**

The aged-adjusted incidence of vaccine-related side effects in vaccinated people compared with that in unvaccinated general population.

Timepoint

2-3 months after vaccination

Method of measurement

Counting those who may have side-effects

2**Description**

To assess the age-adjusted mortality rate from COVID-19 in vaccinated people compared with that in unvaccinated general population.

Timepoint

2-3 months after vaccination

Method of measurement

Counting dead people

3**Description**

To assess the disease severity in those with COVID-19 in vaccinated and unvaccinated people.

Timepoint

2-3 months after vaccination

Method of measurement

Assessed by the 8-point scale used by NIH

Intervention groups**1****Description**

Intervention group: All people receiving health care services from PIHO residing in Fars, Hormozgan, and Ahwaz centers. The intervention group individuals will receive 4 drops of OPV vaccine (provided by Razi Institute). We will follow the age-adjusted incidence rate

of COVID-19 in the study group for at least 2 months after the vaccination.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Petroleum Industry Health Organization

Full name of responsible person

Farrokh Habibzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Petroleum Industry Health Organization

Full name of responsible person

Habibollah Sami

Street address

CEO, PIHO Headquarters, No 75, Behafarin St, Karim Khan Zand Blvd, Vali Asr Sq, Tehran, Iran

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1593816384

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Petroleum Industry Health Organization

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Petroleum Industry Health Organization

Full name of responsible person

Farrokh Habibzadeh

Position

Managing Director, R&D Headquarters

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Petroleum Industry Health Organization

Full name of responsible person

Farrokh Habibzadeh

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available