Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 May 2022

Investigating the effectiveness of MMR vaccination The rate of COVID19 in medical staff compared to the control group

Protocol summary

Study aim
Evaluation of the protective effects of MMR vaccine against coronavirus

Design
Clinical trial, parallel groups, randomized, phase 3 on 323 patients

Settings and conduct
The medical and health staff working in Ahvaz will be invited to participate in the study And will enter the study according to the entry and exit criteria and after obtaining informed consent.According to the randomized table, it is divided into two groups and one group is injected with MMR vaccine and the other group does not receive vaccine. Then, the subjects will be followed up according to the national protocols of COVID-19 and the necessary follow-ups and Covid test -19 will be performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria included health care personnel aged 25-65 years, male or female, who are in contact with patients with SARS CoV-2 infection And sign and date the informed consent form. Exclusion criteria included health care personnel with fever, respiratory infection, pregnant women, taking immunosuppressive drugs such as corticosteroids or any serious underlying disease such as malignancy, receiving a live vaccine, or testing positive for COVID-19.

Intervention groups
MMR vaccine injection to the study group

Main outcome variables
Comparison of the incidence of Covid-19 disease in the vaccinated group with the non-vaccinated group

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200802048266N1**
Registration date: **2020-09-22, 1399/07/01**
Registration timing: **prospective**

Last update: **2020-09-22, 1399/07/01**
Update count: **0**

Registration date
2020-09-22, 1399/07/01

Registrant information

Name
souri heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3336 0289

Email address
sourihedari@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-19, 1399/08/29

Expected recruitment end date
2021-01-18, 1399/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of MMR vaccination The rate of COVID19 in medical staff compared to the control group

Public title
The effect of MMR vaccine in preventing Covid disease

19

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ahvaz health personnel with the age of 25-65 years

Exclusion criteria:

People with defective immune systems MMR vaccine susceptibility Taking immunosuppressive drugs such as corticosteroids Pregnant women People who are not allowed to get the MMR vaccine People who have active cancer and are receiving chemotherapy or radiotherapy. People who have had an organ transplant and are receiving immunosuppressive drugs. People with active HIV infection .

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **323**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization is used and the size of the blocks is randomly selected (for example, blocks of 8, 6, or 10 that contain an equal number of each group in each block).So that the number of samples assigned to each of the study groups is equal. In this method, the blocks are determined based on the personal characteristics of the staff of Ahwaz Health Centers in the face of Covid 19.Within each block, half of the individuals are considered as intervention groups and half as controls. The main goal of this method is to balance the number of participants in each group.In the intervention group, the MMR vaccine will be given to prevent COVID-19 complications, but in the control group, the vaccine will not be used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundipur University of Medical Sciences

Street address

golastan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2020-07-25, 1399/05/04

Ethics committee reference number

IR.AJUMS.REC.1399.361

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

Weight

Timepoint

The beginning of the study

Method of measurement

kilograms

2

Description

WBC

Timepoint

At the beginning and end of the study

Method of measurement

Flow cytometry

3

Description

Lymphocyte count / percentage in CBC

Timepoint

At the beginning and end of the study

Method of measurement

Flow cytometry

4

Description

Anti measles antibody titer

Timepoint

At the beginning and end of the study

Method of measurement

Eliza test

5

Description
Anti rubella antibody titer
Timepoint
At the beginning and end of the study
Method of measurement
Eliza test

6

Description
Anti mumps antibody titer
Timepoint
At the beginning and end of the study
Method of measurement
Eliza test

7

Description
Anti SARS-CoV-2 IgG & IgM
Timepoint
At the beginning and end of the study
Method of measurement
Eliza test

8

Description
PCR test
Timepoint
At the beginning and end of the study
Method of measurement
RT-PCR test using nasopharyngeal swabs

9

Description
Reduce the need for intubation
Timepoint
At the beginning and end of the study
Method of measurement
View

10

Description
Mortality rate
Timepoint
At the beginning and end of the study
Method of measurement
View

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Health workers exposed to the epidemic virus (COVID-19) who were randomly selected after registering personal information including name, gender, age, weight, place of residence, occupation, presence of underlying diseases And disease characteristics were randomly divided into one of two experimental and control groups based on AB and BA random block design. Is placedIf their antibody level is not safe for measles, mumps or rubella, the vaccine will be injected. It is injected according to the protocol of the Ministry of Health. External substance prescribed: MMR vaccine - Participants in the intervention group will receive a dose of MMR vaccine at the rate of 0.5 cc by subcutaneous method (SC)Then, in three periods of two, six and twelve months, the results of the desired indicators are collected. In addition, all subjects in both groups will be routinely searched for signs and symptoms associated with acute respiratory infection / Covid-19. Also, at baseline and 12 months later, serum interferon gamma levels and antibody titers against measles, rubella, and mumps, and if available, IgG and IgM antibody titers against SARS-CoV-2 swabs for PCR measurement. Is taken
Category
Prevention

2

Description
Control group: Health workers exposed to the epidemic virus (COVID-19) who were randomly selected after registering personal information including name, gender, age, weight, place of residence, occupation, presence of underlying diseases And disease characteristics were randomly divided into one of two experimental and control groups based on AB and BA random block design. Is placed.In this group, the vaccine is not injected to evaluate the efficacy of MMR vaccine in the intervention group.Then, in three periods of two, six and twelve months, the results of the desired indicators are collected. In addition, all subjects in both groups will be routinely searched for signs and symptoms associated with acute respiratory infection / Covid-19. Also, at baseline and 12 months later, serum interferon gamma levels and antibody titers against measles, rubella, and mumps, and if available, IgG and IgM antibody titers against SARS-CoV-2 swabs for PCR measurement. Is taken
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahwaz Jundishapur University of Medical Sciences
Full name of responsible person
Souri Heidari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Muhammad Badavi
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Ahvaz University City-Deputy of research and technology Ahwaz Jundishapur University of Medical Sciences and Health Services
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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
Ahvaz University of Medical Sciences
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Souri Heidari
Position
Employee
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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 more 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