

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effects of Covexir(R) capsule on the immune system in healthy volunteers

Protocol summary

Study aim

Determining the effect of Covexir(R) on the immune system in healthy volunteers

Design

Phase 1 randomized double-blinded placebo parallel clinical trial on 32 patients; Randomization using Randaomaization.com.

Settings and conduct

This study is performed on healthy people referring to pharmacies and medical clinics of Mashhad University of Medical Sciences. Physicians, patients, and data analysts are unaware of the medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy volunteers; Male or Female; Age more than 18 years old; Consent to admission to the study; Three injections of the inactivated Covid-19 vaccines and at least two months have passed since the last injection; Not being infected with Covid-19 by using a rapid corona test and evaluating clinical symptoms. Exclusion criteria: Having any diseases; Taking other medications; Taking any herbal products and supplements; Taking Covexir (R) within the previous 6 months.

Intervention groups

Intervention group: receiving Covexir (R) capsule 350 mg once a day for 30 days Placebo group: receiving placebo of Covexir (R) capsule once a day for 30 days

Main outcome variables

Evaluation of parameters related to the immune system (including hs-CRP level)

General information

Reason for update

Due to the difficulty in collecting samples, both males and females will be used in the sampling. In addition, due to the lack of cooperation of patients in providing blood samples after two weeks and the increase in laboratory costs, the evaluation period will be conducted

at the beginning and end of the study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038199N13**

Registration date: **2023-02-28, 1401/12/09**

Registration timing: **prospective**

Last update: **2024-12-18, 1403/09/28**

Update count: **1**

Registration date

2023-02-28, 1401/12/09

Registrant information

Name

Vahid Reza Askari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2264

Email address

askariv941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2026-03-05, 1404/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effects of Covexir(R) capsule on the immune system in healthy volunteers

Public title

Evaluation of effects of Covexir(R) on the immune system in healthy volunteers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age more than 18 years old Healthy volunteers (Confirmed by history, physical examination and routine blood tests) Consent to admission to the study Three injections of the inactivated Covid-19 vaccines and at least two months have passed since the last injection. Not being infected with Covid-19 by using a rapid corona test and evaluating clinical symptoms.

Exclusion criteria:

Having any diseases Taking other medications Taking any herbal products and supplements Taking Covexir (R) within the previous 6 months

Age

From **18 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 8 blocks according to the sample size of 32. Then random numbers between 1 and 8 are selected according to the randomization site Randomaization.com, and finally, the treatment allocation list is determined based on the random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Deputy of Research and Technology of the University, Qurashi Building, Next to Hoveyzeh Cinema, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.MUMS.REC.1401.292

Health conditions studied

1

Description of health condition studied

Healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Evaluation of parameters related to the immune system (including hs-CRP level)

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

Secondary outcomes

1

Description

Interleukin-6 level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

2

Description

Interleukin-10 level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

3

Description

TNF- α level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

4

Description

Immunoglobulin-E level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

5

Description

Immunoglobulin-A level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

6

Description

Immunoglobulin-M level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

7

Description

Immunoglobulin-G level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

8

Description

Immunoglobulin-D level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

9

Description

Changes in CBC diff level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

10

Description

Alanine transaminase (ALT) level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

11

Description

Aspartate transaminase (AST) level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

12

Description

BUN level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

13

Description

Creatinine level

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: Healthy volunteers receiving Covexir at a dose of 350 mg once daily for 30 days.

Category

Treatment - Drugs

2**Description**

Control group: Healthy volunteers receiving placebo capsules of the same shape and size as Covexir once a day for 30 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinics affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Dr Vahid Reza Askari

Street address

Mashhad University of Medical Science, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2000

Email

askariv@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Deputy of Research and Technology of the University
, Qurashi Building, Next to Hoveyzeh Cinema,
University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

ramresearch@mums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of medicine, Paradise of University, Vakil-
Abad Blvd., Azadi Sq., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv941@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of medicine, Paradise of University, Vakil-
Abad Blvd., Azadi Sq., Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv941@mums.ac.ir

Postal code

9177948564

Phone

+98 51 3800 2264

Fax**Email**

askariv941@mums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Vahid Reza Askari

Position

Assistant professor of clinical pharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street addressFaculty of medicine, Paradise of University, Vakil-
Abad Blvd., Azadi Sq., Mashhad**City**

Mashhad

Province

Razavi Khorasan

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