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 Randomaization.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-a 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

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 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

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