# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

23 Feb 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)

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+98 51 3800 2264

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askariv941@mums.ac.ir

**Recruitment status**
**recruiting**

**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
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9177948564
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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
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Deputy of Research and Technology of the University , Qurashi Building, Next to Hoveyzeh Cinema, University Street
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**Phone**
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**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
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
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Assistant professor of clinical pharmacology
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## 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