

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The evaluation of the effect of COVID-19 vaccination on calprotectin levels in IBD patients: A quasi-experimental study

Protocol summary

Study aim

Determining the effect of Covid 19 vaccine injection on calprotectin levels in patients with intestinal inflammation

Design

Phase 2 quasi-experimental study on 30 patients.

Settings and conduct

In 30 patients with IBD who have a file in the Gastroenterology Center of Isfahan University of Medical Sciences and are under constant monitoring, the level of calprotectin and the level of disease severity will be evaluated and compared before and after the injection of the Covid-19 vaccine. These patients will be monitored one to fifteen days before, and also two weeks and twelve weeks after the vaccination to assess the persistence of inflammation and disease severity after the vaccination, and the relevant tests will be performed.

Participants/Inclusion and exclusion criteria

30 IBD patients registered in the gastrointestinal health clinic who are willing to cooperate in completing the questionnaire and secondary follow-up and are over 18 years old.

Intervention groups

Patients with inflammatory bowel disease are evaluated for calprotectin levels before and after the Covid-19 vaccination.

Main outcome variables

Calprotectin levels; Illness severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210113050024N3**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **prospective**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Nazila Kassaian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3237 4705

Email address

nkassaian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of COVID-19 vaccination on calprotectin levels in IBD patients: A quasi-experimental study

Public title

The evaluation of the effect of COVID-19 vaccination on calprotectin levels in IBD patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The IBD patients Willing to cooperate in completing the questionnaire and secondary follow-up Be over 18 years old.

Exclusion criteria:

Patient non-cooperation The patient is in a state of recurrence and has symptoms of bleeding and fever during this period

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib St., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-30, 1400/06/08

Ethics committee reference number

IR.MUI.MED.REC.1400.417

Health conditions studied**1**

Description of health condition studied

Inflammatory Bowel Disease

ICD-10 code

K52

ICD-10 code description

Other and unspecified noninfective gastroenteritis and colitis

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

Fecal chlorprotectin levels

Timepoint

The calprotectin level is checked one to fifteen days before the Covid-19 vaccination and also two weeks and twelve weeks after receiving the vaccine.

Method of measurement

Fecal calprotectin levels are assessed using ELISA kits.

2**Description**

Illness severity

Timepoint

One to fifteen days before the Covid-19 vaccination and two weeks and twelve weeks after receiving the vaccine.

Method of measurement

Lichtiger and Mayoscore questionnaire

Secondary outcomes

empty

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

Intervention group: Patients with intestinal inflammation who receive the first dose of the Covid-19 vaccine.

Category

Rehabilitation

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

Isfahan Gastroenterology and hepatology Research Center

Full name of responsible person

Babak Tamizifar

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Hezar Jerib St., Isfahan University of Medical Sciences, Gastroenterology and Hepathology Research Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Babak Tamizifar

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Ph.D.

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Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of the results is allowed in coordination with the executor

From where data/document is obtainable

To receive project documents or data, contact Dr. Babak Tamizifar at: babaktamizifar@gmail.com Phone: 00989133257859

What processes are involved for a request to access data/document

Data return is done by written request and acceptance of the conditions by email or phone.

Comments