

# Association between inflammatory bowel disease and other autoimmune disorders

<b>Submission date</b> 30/11/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/01/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Inflammatory Bowel Disease (IBD) includes two types of chronic conditions, Ulcerative Colitis (UC) and Crohn's disease. IBD makes the intestines swollen and painful. The cause of IBD is not known, but it is believed that a person's immune system, genetic differences, and environmental factors may contribute to it.

This study aims to find out how common autoimmune disorders are in patients with IBD at a hospital in Riyadh, Saudi Arabia. The researchers will look at data from a specific point in time, to see how many patients have been diagnosed with both IBD and other autoimmune disorders. The study will help healthcare professionals better understand the prevalence of these disorders and how to treat them.

### Who can participate?

This study is looking for adult patients who have been diagnosed with either Crohn's disease (CD) or ulcerative colitis (UC) based on internationally recognized standards.

### What does the study involve? (for participants)

We will conduct a study in Riyadh, the capital city of Saudi Arabia, at a healthcare center that provides comprehensive care to patients with Inflammatory Bowel Disease (IBD). The center offers diagnosis, treatment, and follow-up services, and we will use medical records to gather data for our research. Our study will involve a focused and similar group of participants, allowing us to accurately assess our research objectives within the allotted time frame.

### What are the possible benefits and risks of participating?

We're conducting a study in Saudi Arabia to determine the frequency of autoimmune disorders in IBD patients. This will help healthcare providers optimize care and treatment strategies for patients with IBD and autoimmune disorders. As a descriptive study, there is no risk involved.

### Where is the study run from?

King Fahad Medical City (Saudi Arabia)

### When is the study starting and how long is it expected to run for?

September 2023 to December 2023

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Ahmed Alghamdi, [agalghamdi@kfmc.med.sa](mailto:agalghamdi@kfmc.med.sa)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Ahmed Alghamdi

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

## Study information

### Scientific Title

Prevalence of coexisting autoimmune disorders among inflammatory bowel disease (IBD) patients at a tertiary care centre in Riyadh, Saudi Arabia: a cross-sectional study

### Study objectives

The study aims to assess the prevalence of coexisting autoimmune disorders among IBD patients

### Ethics approval required

Ethics approval required

**Ethics approval(s)**

Approved 12/09/2023, King Fahad Medical City (P.O. Box. 59046, Riyadh, 11525, Saudi Arabia; +966 11 288 9999 Ext: 15789; hsakkijha@kfmc.med.sa), ref: H-01-R-012

**Study design**

Observational cross-sectional study

**Primary study design**

Observational

**Secondary study design**

Cross sectional study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Prevalence of coexisting autoimmune disorders among IBD patients

**Interventions**

The study will be conducted in Riyadh, the capital of Saudi Arabia, at a tertiary care center offering comprehensive care to many IBD patients, including diagnosis, treatment, and follow-up. Access to medical records within this setting will provide rich data sources. The study settings will ensure a focused and homogeneous group of participants, facilitating an accurate assessment of our research objectives within the given time frame

**Intervention Type**

Not Specified

**Primary outcome measure**

Coexisting autoimmune disorders among (IBD) patients measured using patient records at a single time point

**Secondary outcome measures**

Disease severity and disease complication measured using patient records at a single time point

**Overall study start date**

01/09/2023

**Completion date**

30/12/2023

**Eligibility**

**Key inclusion criteria**

1. Patients diagnosed with either CD or UC based on internationally recognized criteria.
2. Age 14 years or above.
3. IBD is currently being treated at a specialized medical facility.
4. Availability of complete medical records for data extraction.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

14 Years

**Upper age limit**

75 Years

**Sex**

Both

**Target number of participants**

400

**Key exclusion criteria**

1. Patients with an incomplete diagnosis of IBD.
2. Patients with a history of primary immunodeficiency disorders.
3. Patients who have received solid organ or bone marrow transplantation.

**Date of first enrolment**

13/09/2023

**Date of final enrolment**

15/10/2023

**Locations****Countries of recruitment**

Saudi Arabia

**Study participating centre**

King Fahad medical city

Khurais Road

Riyadh

Saudi Arabia

11525

# Sponsor information

## Organisation

King Fahad Medical City

## Sponsor details

Khurias Road

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Saudi Arabia

11525

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## Sponsor type

Government

## Website

<https://www.kfmc.med.sa/#>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

The Journal of Research in Inflammatory Bowel Disease

The Journal of Research in Gastroenterology and Hepatology

## Intention to publish date

01/01/2024

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

aalghamedi80@gmail.com

## IPD sharing plan summary

Available on request

