

Association between inflammatory bowel disease and other autoimmune disorders

Submission date 30/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/01/2024	Condition category 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

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

14 years

Upper age limit

75 years

Sex

All

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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