pcori PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE RESEARCH SUMMARY

PROJECT INFORMATION

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Do Medicines for Inflammatory Bowel Disease Affect the Risk of COVID-19 Infection?

Principal investigator

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In response to the COVID-19 public health crisis in 2020, PCORI launched an initiative to enhance existing research projects so that they could offer findings related to COVID-19. The initiative funded this study and others.

What was this COVID-19 study about?

With inflammatory bowel disease, or IBD, the immune system harms healthy cells in the body. Patients with IBD have symptoms like stomach pain and long-term diarrhea.

To treat IBD, people can take different types of medicine that limit the body's immune system response. But these medicines may lower the body's defenses and increase the chance of getting severe COVID-19.

This study had two parts. First, the research team wanted to learn if taking IBD medicines increased the chance of getting COVID-19 infection. They looked at seven types of IBD medicines:

- Corticosteroids
- Aminosalicylates
- Thiopurines
- Anti-integrins
- Janus kinase (JAK) inhibitors

- **Organization** The University of North Carolina at Chapel Hill
- Anti-interleukin (anti-IL) 12/23s
- Anti-tumor necrosis factor (TNF) agents

Second, the research team looked at how these medicines affected the risk that patients would have a hospital stay, be placed on a ventilator, or die due to COVID-19.

What were the results?

COVID-19 infection rates didn't differ between patients who did and didn't use IBD medicines.

Compared with patients who didn't use corticosteroids, patients who used them had a higher risk of:

- Having a hospital stay due to COVID-19
- Being placed on a ventilator due to COVID-19
- Dying due to COVID-19

Patients who used anti-TNF or aminosalicylate medicines had a lower risk of going to the hospital due to COVID-19 than patients who didn't use them. The other medicines weren't related to the study outcomes.

Who was in the study?

The first part of the study included 3,953 adult patients with IBD. Of these patients, 99 percent were White,

and 1 percent were African American. The average age was 47, and 67 percent were women.

The second part looked at insurance claims for 102,986 patients enrolled in two large, national health plans. The average age was 53, and 55 percent were women.

What did the research team do?

In the first part of the study, the research team sent online surveys to patients with IBD who were already participating in ongoing studies sponsored by the Crohn's and Colitis Foundation. The surveys asked about other illnesses, medicine use, and COVID-19 test results between April 2020 and August 2021. The team sent surveys at the start of the study; two, four, six, and eight weeks later; and then every six months.

In the second part, the research team reviewed insurance claims data for patients with IBD between August 2019 and August 2021. The team looked at the types of IBD medicines patients used, hospital stays, use of ventilators, and deaths from COVID-19.

What were the limits of the study?

People started to receive COVID-19 vaccines during the study. Vaccines may have affected the number of COVID-19 infections or COVID-19 severity. The research team didn't assign patients to IBD medicine or no IBD medicine by chance. As a result, the team can't say for sure whether the IBD medicines caused the outcomes studied.

How can people use the results?

Patients with IBD can use the results to help understand their risk of having severe COVID-19 when taking medicines for IBD.

To learn more about this project, visit www.pcori.org/Kappelman446. This project is part of a larger study, Comparing Treatments for Patients with Inflammatory Bowel Disease Who Don't Respond to Anti-TNF Therapy.

The research reported in this results summary was conducted using PCORnet[®], the National Patient-Centered Clinical Research Network. PCORnet[®] is intended to improve the nation's capacity to conduct health research, particularly comparative effectiveness research (CER), efficiently by creating a large, highly representative network for conducting clinical outcomes research. PCORnet[®] has been developed with funding from the Patient-Centered Outcomes Research Institute[®] (PCORI[®]).

WWW.PCORI.ORG/KAPPELMAN446

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