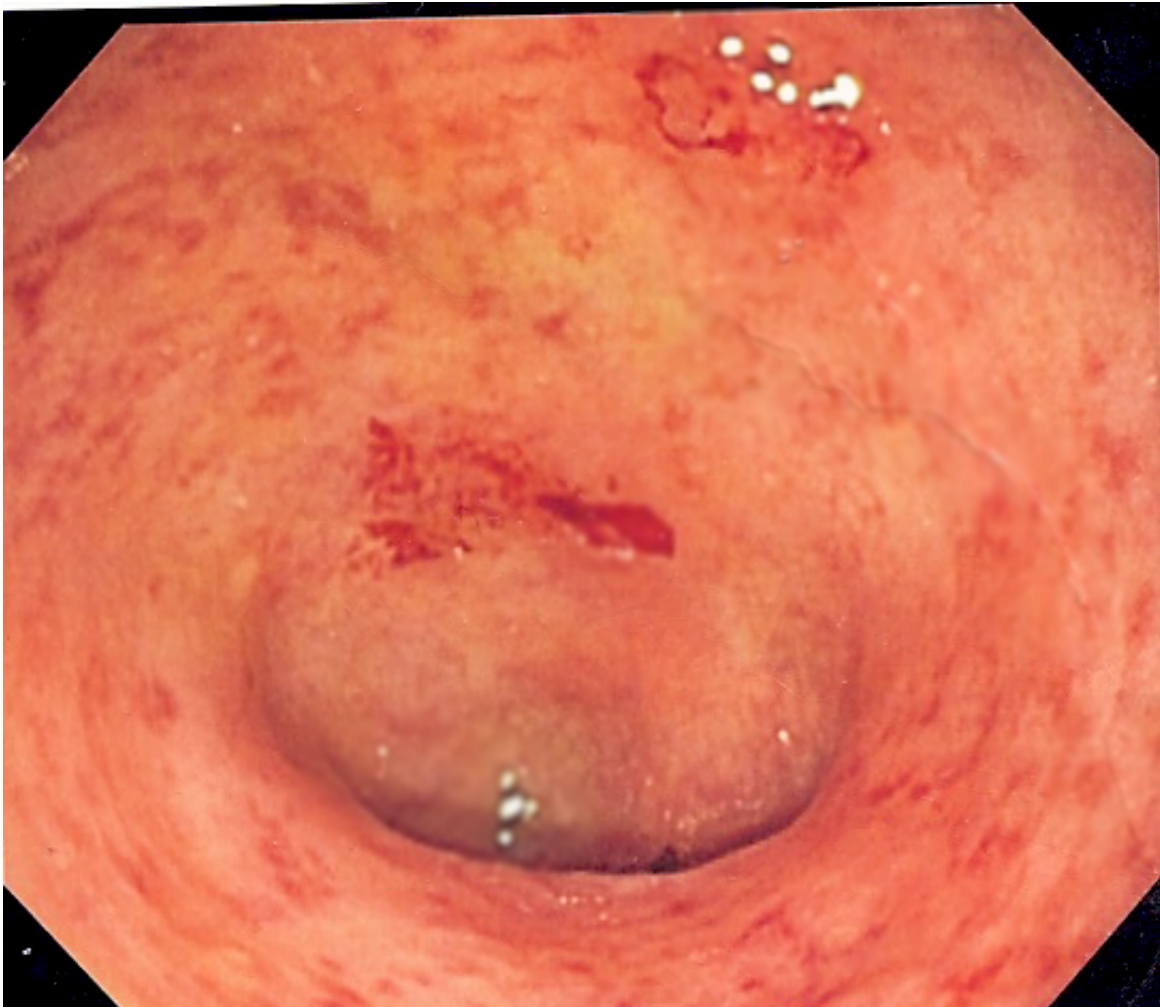


# New drug application doubles rates of remission in patients with ulcerative colitis

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Endoscopic image of a bowel section known as the sigmoid colon afflicted with ulcerative colitis. The internal surface of the colon is blotchy and broken in places. Credit: Samir/Wikipedia

A new drug, investigated by Amsterdam University Medical Centers together with colleagues around the world, is effective as a treatment against ulcerative colitis. With the clinical trial demonstrating a doubling in the rates of remission, to up to 50%, in certain groups. The results of this clinical trial were published in the *New England Journal of Medicine*.

Around the world, it is estimated that millions live with ulcerative colitis, a condition that is only growing in prevalence. Geert D'Haens, lead author and Professor of Gastroenterology at Amsterdam UMC, says, "there is still a high unmet need for safe and effective treatments for ulcerative colitis. This new medicine meets this need for an important proportion of patients"

Ulcerative colitis is a common chronic disease of the colon. Patients have bloody diarrhea, [abdominal pain](#), anemia and fatigue. Many patients have an impaired quality of life and current treatments cannot always control the disease. In that case, patients need to undergo surgery (colectomy) with a stoma or a pouch-construction. Chronic inflammation of the colon is also associated with an increased risk of cancer.

Researchers identified Interleukin-23 as a very important protein in triggering and maintaining gut inflammation, both in Crohn's disease and ulcerative colitis and also in the chronic skin disease psoriasis. Previously it has been shown that blocking interleukin-23 with specific therapeutic antibodies is highly effective for those with psoriasis and Crohn's disease. Mirikizumab is the first such antibody that was tested for ulcerative colitis.

## **Clinical trial**

In recent years, a large group of researchers from around the globe

performed two Phase 3 [clinical trials](#) to assess the safety and efficacy of mirikizumab in 1,281 adult ulcerative colitis patients with moderate to severe inflammation. For comparison, a "control group" of comparable ulcerative colitis patients was not treated with mirikizumab but with a [placebo](#).

Patients received 300 mg mirikizumab or placebo (in a 3:1 ratio) via an infusion every four weeks for 12 weeks in total (LUCENT-1 study). If patients responded to mirikizumab in these 12 weeks (544 out of 1281 patients), they continued in the LUCENT-2 study where they received 200mg mirikizumab or placebo (in a 2:1 ratio) via an injection every four weeks for 40 additional weeks.

## Little to no side effects

Patients who were treated with mirikizumab were more likely to achieve clinical remission at both the end of the LUCENT-1 and LUCENT-2 than patients treated with placebo (LUCENT-1 24.2% versus 13.3% and LUCENT-2 49.9% versus 25.1%). The patients that received mirikizumab also had higher clinical response, endoscopic remission, and less bowel movement urgency. Interestingly, mirikizumab treatment appeared very safe. Adverse events were not more common with mirikizumab than with placebo treatment.

"If we combine these results together, we see that mirkizumab is an effective drug for those patients with moderately severe and severe forms of [ulcerative colitis](#). We hope that it will be available as a treatment option in Europe this year," concludes D'Haens.

**More information:** Mirikizumab as Induction and Maintenance Therapy for Ulcerative Colitis, *New England Journal of Medicine* (2023).

Provided by Amsterdam University Medical Centers

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