What can we learn from ADMIRE?

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UEG Week Barcelona 2026 | Presentation

IBD

October 19, 2026

The ADMIRE 2 trial failed to demonstrate benefit of mesenchymal stem cell therapy over placebo for perianal fistulizing Crohn's disease, unlike ADMIRE 1 a decade earlier, likely due to substantial evolution in standard medical care between the trials.

KEY POINTS

- In ADMIRE 1, the treated group achieved the primary endpoint of combined remission at week 24 in 50% versus over 30% for placebo, while in ADMIRE 2 both treated and placebo groups achieved roughly 50% remission, eliminating the treatment difference.
- The speaker identified evolving medical treatment as the key difference between trials: in ADMIRE 2, only 3.5% of patients received no medical therapy versus 24% in ADMIRE 1, and 55% received monoclonal antibody monotherapy versus 35% in ADMIRE 1.
- More than 90% of ADMIRE 2 patients received biologic therapy and over half received combination therapy, reflecting substantially improved standard care for perianal fistulizing Crohn's disease over the decade between trials.
- Both trials used identical designs including fistula tract cleaning, product injection, and internal fistula closure, with a primary endpoint of clinical closure of all external openings and absence of collections larger than 2 cm confirmed by MRI at week 24.
- The speaker suggested the strategy of draining and cleaning the fistula tract, internal closure, and good medical treatment may be a good option for complex fistulas, and that better medical strategies now achieve similar results.
- The speaker noted that determining which patient subgroups might benefit from stem cell therapy remains an open research question, but acknowledged uncertainty about who would conduct such trials.

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