

Novel Budesonide Suppository and Standard Budesonide Rectal Foam Induce High Rates of Clinical Remission and Mucosal Healing in Active Ulcerative Proctitis: a Randomised, Controlled, Non-inferiority Trial

Randomised, double-blindm double-dummy, active-controlled non-inferiority trial.
Patients with mild-moderate UC proctitis were randomized to budesonide suppository (BUS) 4 gr or budesonide 2gr rectal foam (BUF) for 8 weeks.
The non-inferiority margin between the remission rate in both treatment groups was set at 10%.

Primary endpoint: Clinical remission and mucosal healing

Results: N=577

- Clinical remission was 78.8 BUS 5gr vs 74.3% BUF 2 gr.
- Mucosal healing was 81.2% BUS vs 81.2% BUF.

Conclusion:

In patients with ulcerative proctitis, budesonide 4 mg suppository was non-inferior to budesonide 2 mg foam in efficacy, and both were safe and well tolerated.

