

Randomized double-blind, placebo-controlled trial. Patients with refractory pouchitis for more than 4 weeks in spite of antibiotic treatment were randomized to adalimumab or placebo for 12 weeks.

Primary outcome: Reduction in clinical pouchitis disease activity index (PDAI) of ≥ 2 at any time.

Results: N=13

- Nine patients completed the 12 week program.
- Reduction in clinical PDAI ≥ 2 was achieved in 50% adalimumab and 43% placebo, p=ns
- Total improvement in PDAI 100% adalimumab and 29% placebo, p=ns

Conclusion:

In this RCT adalimumab did not show to be better than placebo in any primary or secondary outcome

**Adalimumab in the treatment of chronic pouchitis.
A randomized double-blind, placebo-controlled trial**

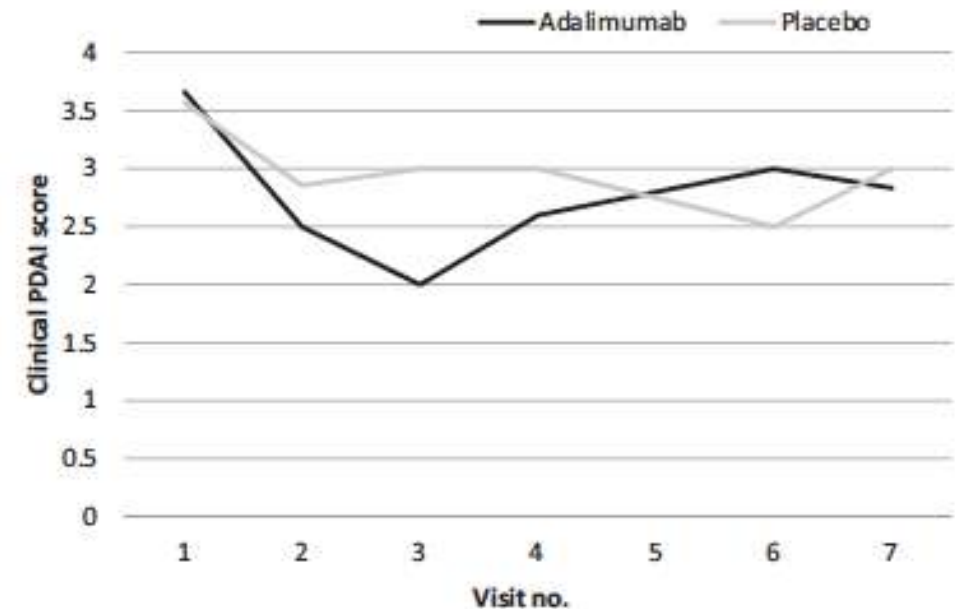


Figure 2. Clinical Pouchitis Disease Activity Index (PDAI). No.: Number.

