2007. Topical Tacro pCD

RCT/Topical tacrolimus/pCD/Induction

Topical Tacrolimus in the Treatment of Perianal Crohn's Disease: Exploratory Randomized Controlled Trial

4-week, placebo-controlled, double-blind trial.

Patients active perianal CD stratified in 7 with ulcerating and 12 with fistulizing were randomized to topical tacrolimus 1mg/g (1g ointment twice a day) or placebo for 12 weeks.

Primary endpoint: In ulcerating disease was global improvement in the perianal/anal lesions; for fistulas it was the reduction of ≥50% of actively draining fistulas on 2 consecutive visits.

Results: N=19

- Ulcerating disease: 3/4 tacrolimus improved vs 0/3 placebo. Complete healing was not achieved.
- Fistulising disease: 2/6 on tacrolimus developed abscesses
- Whole blood tacrolimus levels were detectable only in 2 patients and were low.

Conclusion:
These preliminary data suggest that topical tacrolimus is effective and safe in the treatment of perianal or anal ulcerating CD. This therapy is unlikely to be beneficial in fistulizing perianal Crohn's disease, although a larger study is required to confirm this.

TABLE 3. 12-Week Outcome in Fistulizing Disease and Ulcerating Disease

A: Global outcome in fistulizing disease

Fistulizing disease (n = 12)	Partial response	Complete response	Global improvement	Stable disease
Tacrolimus (n = 6)	0	1	1	4
Placebo (n = 6)	1	0	1	4

B: Fistulizing disease: outcome of treated patients

Patient No.	Partial response (Y/N)	Complete response (Y/N)	Global improvement (Y/N)	Seton at baseline (Y/N)	Adverse events
Tacrolimus					
1	N	N	Y	N	Abscess week 12
2	N	N	N	Y	None
3	N	N	N	Y	Abscess week 4
4	N	Y	Y	Y	None
5	N	N	N	Y	Local skin irritation
6	N	N	N	N	Withdrew week 8, lack of efficacy
Placebo					
1	N	N	N	Y	Local skin irritation
2	N	N	N	N	None
3	Y	N	Y	Y	Local skin irritation
4	N	N	N	Y	None
5	N	N	Y	Y	Local skin irritation
6	N	N	N	Y	None

C: Global outcome in ulcerating disease (12 weeks)

Ulcerating disease (n = 7)	Global improvement	Complete healing	Stable disease
Tacrolimus (n = 4)	3	0	1 Noncompliant
Placebo (n = 3)	0	0	3

Hart AL et al. Inflamm Bowel Dis. 2007; 13: 245-253