

Summary

Primary endpoint:

High dose vitamin D treatment did not affect the mucosal mRNA expression of VDR, IL17A, IL17F and IL22, however 7 weeks of infliximab treatment reduced the expression of IL17F and IL22 (see table 1 below, estimates are median ratio). There was no significant difference between the infliximab+vitamin D group and the infliximab+placebo group in mRNA expressions. IL4 was not detectable in mucosa.

Secondary endpoints:

High dose vitamin D alone and combined with infliximab decreased the mRNA expression of IL10, whereas infliximab without vitamin D did not (see table 1). Also interferon gamma expression was decreased by vitamin D but also by infliximab.

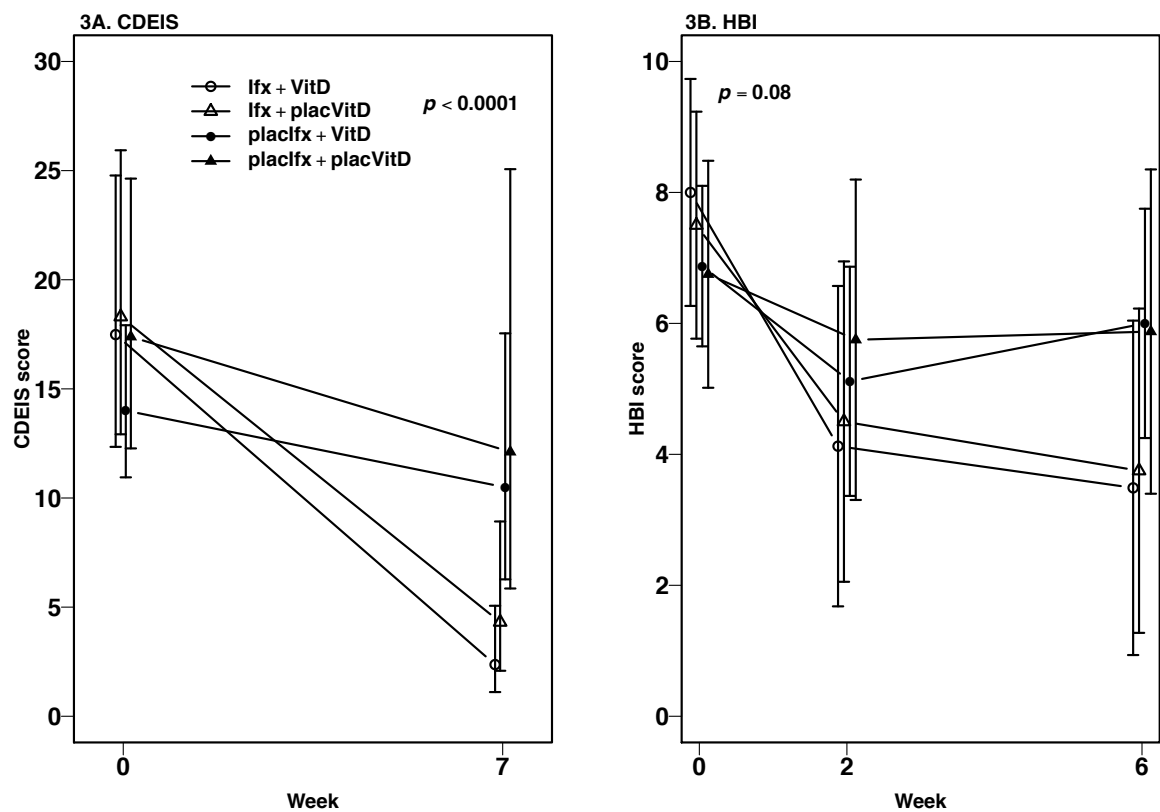
Disease activity measured in CDEIS score, HBI score calprotectin and CRP was not affected by high dose vitamin D treatment during the intervention (week 0 to 7). There was no significant difference between the plac-infliximab+vitamin D group and plac-inf+plac-vitamin D group. The two infliximab groups significantly decreased in disease activity compared to placebo.

During follow up where all patients were treated with infliximab open, the two groups who were treated with high dose vitamin D during the intervention had lower CRP and calprotectin levels compared to the two groups who were initially treated with placebo vitamin D.

Table 1

Gene	1. Infix + vitD		2. Infix + placebo-vitD		3. Placebo-infix + vitD		4. Placebo infix+placebo vitD	
	W0/W7 (95%CI)	p-value	W0/W7 (95%CI)	p-value	W0/W7 (95%CI)	p-value	W0/W7 (95%CI)	p-value
IL22	0.03 (0.005 - 0.12)	0.00001	0.12 (0.03 - 0.46)	0.002	0.47 (0.17 - 1.26)	0.13	0.57 (0.12 - 2.62)	0.47
VDR	0.7 (0.34 - 1.45)	0.34	0.83 (0.42 - 1.67)	0.61	1.37 (0.84 - 2.22)	0.21	0.72 (0.32 - 1.62)	0.42
IL17F	0.25 (0.11 - 0.6)	0.002	0.36 (0.16 - 0.81)	0.013	0.92 (0.5 - 1.69)	0.78	0.97 (0.39 - 2.44)	0.95
IL17A	0.31 (0.06 - 1.45)	0.14	0.64 (0.14 - 2.96)	0.57	0.74 (0.19 - 2.93)	0.67		
TGFbeta	0.82 (0.45 - 1.52)	0.53	0.73 (0.41 - 1.29)	0.28	0.70 (0.47 - 1.05)	0.09	1.17 (0.59 - 2.31)	0.65
IL10	0.49 (0.27 - 0.88)	0.02	0.75 (0.43 - 1.3)	0.31	0.63 (0.43 - 0.93)	0.02	0.92 (0.48 - 1.75)	0.80
IFNg	0.21 (0.07 - 0.59)	0.003	0.37 (0.14 - 1.00)	0.05	0.47 (0.23 - 0.95)	0.03	0.96 (.30 - 3.02)	0.94
TNFalpha	0.61 (0.32 - 1.13)	0.12	0.47 (0.25 - 0.85)	0.01	0.68 (0.45 - 1.03)	0.07	1.20 (0.59 - 2.45)	0.62

Figure 1



Disease activity measured by endoscopic score CDEIS and by Harvey-Bradshaw index.