Adalimumab). Clinical response rates were significantly higher in the anti-TNF group (74% vs 62%, p=0.04). Similarly, radiological response rates were higher in the anti-TNF group (56% vs 28%, p<0.01).

Cox Regression analysis demonstrated fistula duration (p=0.01) and biologic therapy (p=<0.01) to be significant at the univariate level. At the multivariate level, patients on anti-TNF therapy had a faster radiological response over a 6-year follow-up period (OR=2.25, CI= 1.14-4.46, p=0.02). A short duration of CD (less than 5 years) contributes to a faster time to clinical response (OR=1.77, CI=1.03-3.05, p=0.04).

Treatment with anti-TNF therapy is an independent predictor of radiological response (OR 3.55, CI 1.59-7.91, p<0.01). Patients with L1 luminal disease are 3 times more likely not to go into clinical remission on both univaraite and multivariate analyses (OR=3.08, CI=1.47-6.46, p=0.01). The duration of CD is also a poor predictor of clinical response to therapy (p<0.01).

**Conclusions:** Patients on anti-TNF therapy have improved clinical and radiological response rates compared with patients without. Anti-TNF therapy is a positive predictor of radiological response to therapy.

## P389

## A double-blind clinical trial on *Trichuris suis* ova (TSO) in active Crohn's disease resulted in a significant placebo effect both in patients and investigators without objective evidence of reduced inflammation

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**Background:** A randomized, double blind, placebo controlled phase II study with an planned interim analysis and using 3 doses of TSO in mildly to moderately active ileo-/colonic, uncomplicated Crohn's disease failed to show evidence of a therapeutic benefit regarding remission or response according to the CDAI as compared to placebo, but resulted in an unexpectedly high placebo remission rate of 43% [1]. The goal of this analysis was to explore tentative reasons for this high placebo response.

**Methods:** Primary endpoint was the rate of clinical remission (CDAI<150) at week 12 (LOCF; ITT analysis). Exploratory analyses of baseline data, change of biochemical parameters and components of the CDAI as well as physician global assessment were performed and in particular results of the primary endpoint of the two stages of the study were calculated (see Table 1 for stage definition).

**Results:** There was no effect of any of the baseline parameters analyzed (duration of disease, BMI, sex, age, CDAI) on the remission rate. CRP and calprotectin were initially somewhat more elevated in patients who did not achieve remission, but overall no clinically relevant change from baseline was seen in any of the groups. No significant difference in change of single CDAI components was found between treatment groups. In a small subpopulation of 37 patients mucosal healing was studied and occurred in 2 patients each with 250 TSO and placebo and 1 each in the other two groups. Physicians' global assessment showed success of treatment in 25.4% and benefit in 57.1% of all patients without any difference between groups. Interestingly, the observed clinical remission rates were not consistent between the 2 stages of the study (Table 1).

**Conclusions:** The high clinical remission rate (42.9%) in the placebo group according to CDAI was not accompanied by any relevant change of initially elevated biochemical parameters of inflammation or mucosal healing at endoscopy. This finding casts further doubt on the suitability of the CDAI as sole primary endpoint in Crohn's disease, as it is susceptible to record subjective symptom improvement which is not reflected by biochemical markers and/or endoscopic sign of inflammation. Physicians' global assessment was as well rather positive in all groups. The different remission rates in the two stages might be explained by the low group size in each stage as well as by a potential selection bias in favour of 'believers' in alternative medicine.

*on behalf of the International TSU-2 Study Group (TRUST-2)

### References:

[1] Schölmerich J, et al., (2014), Efficacy and safety of Trichuris suis ova fo rtreatment o fmildly-to-moderately active Crohn's disease: A randomised, double-blind, placebo-controlled, phase II study, UEG Journal, 2(1S):A123 (OP392)

Number (%) of patients with clinical remission (CDA<150) at wk 12 (LOCF). Stage I/II contain patients enrolled before/after the recommendation of the interim analysis, respectively

| | TSO 250 | TSO 2.500 | TSO 7.500 | Placebo | Total |
|---|---|---|---|---|---|
| **Stage I** | 15/39 (38.5%) | 10/39 (25.6%) | 20/39 (51.3%) | 14/39 (35.9%) | 59/156 (37.8%) |
| **Stage II** | --- | 15/32 (46.9%) | 14/33 (42.4%) | 16/31 (51.6%) | 45/96 (46.9%) |
| **Overall** | 15/39 (38.5%) | 25/71 (35.2%) | 34/72 (47.2%) | 30/70 (42.9%) | 104/252 (41.3%) |