

Prospective multicentre, pragmatic, randomised, controlled, open-label, parallel group, superiority trial.

Allocated [1:1:1] to chronic seton drainage, long-term anti-TNF, or surgical closure after anti-TNF induction.

**Primary outcome:** Fistula related re-intervention[s], defined as surgical re-interventions and/ or [re]start of anti-TNF therapy due to suspicion of recurrent abscess or new fistula tract[s] within 1 year.

#### Results:

The study was stopped by the data safety monitoring board because of futility.

- Seton treatment was associated with the highest re-intervention rate [10/15, versus 6/15 anti-TNF and 3/14 surgical closure patients,  $p = 0.02$ ].
- No substantial differences in perianal disease activity and quality of life between the three treatment groups were observed.

#### Conclusion:

The results imply that chronic seton treatment should not be recommended as the sole treatment for perianal Crohn's fistulas

**Table 3.** Re-interventions in RCT and registry patients till end of study, assessed using Kaplan-Meier analyses.

| Re-interventions | Seton drainage<br><i>n</i> [%] | Anti-TNF<br><i>n</i> [%] | Surgical closure<br><i>n</i> [%] |
|------------------|--------------------------------|--------------------------|----------------------------------|
| RCT*             | 10 [74%]                       | 6 [42%]                  | 3 [23%]                          |
| Registry         | 8 [42%]                        | 9 [48%]                  | 2 [44%]                          |

Re-interventions till end of study were significantly higher in the seton group of the randomised patients [ $p$  log-rank = 0.02]

RCT, randomised controlled trial; TNF, tumour necrosis factor.

