

**ORAL PRESENTATION**

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# OA07.03. Randomized, double-blind, double-dummy trial of myrrh, chamomile, coffee charcoal compared to mesalazine in maintaining remission in ulcerative colitis

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## Purpose

We compared the efficacy of the herbal preparation of myrrh, chamomile extract and coffee charcoal (herb) with a mesalazine (mes) therapy in maintaining remission in ulcerative colitis (UC).

## Methods

A total of 96 patients (51 female) with UC in remission (not longer than 12 months) were included in a randomized, double-blind, double-dummy, multicenter, non inferiority study comparing mesalazine 500 mg (3x1/d) to 100mg myrrh, 70mg chamomile extract and 50mg coffee charcoal (3 x 4/d) over a time period of 12 months. As primary outcome criterion, non-inferiority of the herbal preparation was defined and accepted, if the difference in the colitis activity index (Colitis Activity Index - CAI - Rachmilewitz) (calculated at six time points during the 12 month interval) averaged over all visits was  $\leq 1$  point. Furthermore, relapse rates, relapse-free times, safety, a comprehensive activity index (CAI, CRP and fecal Lactoferrin, Calprotectin and PMN-Elastasis), an endoscopic activity index and Health-related Quality of life (HrQoL) were assessed. Peripheral CD4+CD25+ reg T-cells were investigated in a subgroup at each time point and during a flare.

## Results

Primary outcome criterion ( $p = 0.19$ ), relapse rates (CAI>4) (mes 22/49 patients vs herb 25/47 patients;  $p =$

0.54), relapse-free time ( $268 \pm 22$  days for mes and  $240 \pm 23$  days ( $p = 0.40$ ) for the herb), the comprehensive activity index and HrQoL did not show a significant difference. Of notice, peripheral CD4+CD25+ regulatory T-cells showed a distinct different pattern at time points pre-flare and flare for the two treatment modalities (CD4+CD25+T<sub>reg</sub> mes  $p = \text{non significant (ns)}$ ; herb  $p = 0.02$ ; CD4+CD25+ T<sub>reg</sub> high mes  $p = \text{ns}$ ; herb  $p = 0.008$ ).

## Conclusion

The herbal preparation shows efficacy and safety in maintaining remission non-inferior to mesalazine in ulcerative colitis. It appears to offer an alternative option for maintenance therapy. Regulatory T-cell pattern might give first evidence to suggest a different mechanism of action.

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