



# Boswellia serrata extract for the treatment of collagenous colitis: a randomized, double-blind, placebo-controlled, multicenter trial.

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## Background

Collagenous colitis is an idiopathic microscopic colitis characterized by chronic watery diarrhea, a typical subepithelial collagen layer, and lymphoplasmacellular infiltration. Due to their anti-inflammatory properties, Boswellia serrata extract (BSE) have been used in various inflammatory disorders such as bronchial asthma, chronic polyarthritis and inflammatory bowel diseases.

## Aim of the Study

We investigated the effect of BSE on symptoms, quality of life and histology in patients with collagenous colitis in a randomized, double-blind, placebo-controlled multicenter trial.

## Patients and Methods

Patients with chronic diarrhea ( $\geq 5$  times per day) and histologically proven collagenous colitis were randomized to receive either oral Boswellia serrata extract 400 mg three times daily for 6 weeks or placebo. Complete colonoscopy was performed before and after treatment. Histopathology was assessed by a single pathologist blinded to the patients' treatment. Clinical symptoms were assessed by standardized questionnaires. Patients of the placebo group with persistent diarrhea received cross-over BSE therapy.

## Results

31 patients (mean age 59 years, 26 female, 16 verum group) were randomized; 25 patients were available for per protocol analysis.

Six patients (5 verum group) prematurely discontinued treatment due to several reasons: adverse events  $n = 3$  (2 verum group), lost of follow-up  $n = 1$  (verum group), unwillingness to continue  $n = 2$  (verum group).

The rate of clinical remission (frequency of diarrhea  $\leq 3$  times per day) was higher in the Boswellia serrata extract group than in the placebo group (per protocol 63.3% vs. 26.6%, respectively, Figure 1). Six patients received cross-over BSE therapy, five of them showed complete remission after 6 weeks.

Figure 1: Study Design

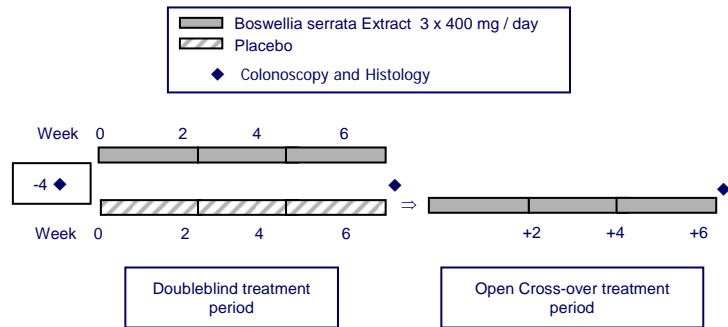
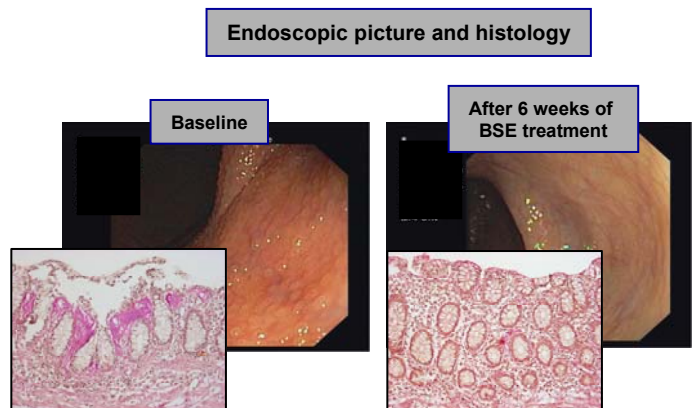
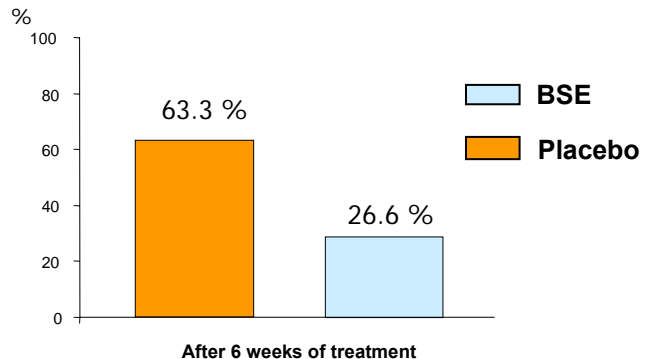


Figure 2: Patients with clinical remission after 6 weeks (per-protocol)



## Conclusions

- Oral Boswellia serrata extract is able to induce clinical remission in patients with collagenous colitis.
- The incidence of adverse events was low.