



ARTICLES | VOLUME 8, ISSUE 5, P408-421, MAY 2023

# One-food versus six-food elimination diet therapy for the treatment of eosinophilic oesophagitis: a multicentre, randomised, open-label trial

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## Summary

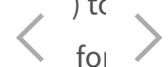
### Background

Empirical elimination diets are effective for achieving histological remission in eosinophilic oesophagitis, but randomised trials comparing diet therapies are lacking. We aimed to compare a six-food elimination diet (6FED) with a one-food elimination diet (1FED) for the treatment of adults with eosinophilic oesophagitis.

### Methods

We conducted a multicentre, randomised, open-label trial across ten sites of the Consortium of Eosinophilic Gastrointestinal Disease Researchers in the USA. Adults aged 18–60 years with active,

symptomatic eosinophilic oesophagitis were centrally randomly allocated (1:1; block size 10) to 1FED (animal milk) or 6FED (animal milk, wheat, egg, soy, fish and shellfish, and peanut and tree nuts). [View full text](#)



weeks. Randomisation was stratified by age, enrolling site, and gender. The primary endpoint was the proportion of patients with histological remission (peak oesophageal count <15 eosinophils per high-power field [eos/hpf]). Key secondary endpoints were the proportions with complete histological remission (peak count  $\leq 1$  eos/hpf) and partial remission (peak counts  $\leq 10$  and  $\leq 6$  eos/hpf) and changes from baseline in peak eosinophil count and scores on the Eosinophilic Esophagitis Histology Scoring System (EoEHSS), Eosinophilic Esophagitis Endoscopic Reference Score (EREFS), Eosinophilic Esophagitis Activity Index (EEsAI), and quality of life (Adult Eosinophilic Esophagitis Quality-of-Life and Patient Reported Outcome Measurement Information System Global Health questionnaires). Individuals without histological response to 1FED could proceed to 6FED, and those without histological response to 6FED could proceed to swallowed topical fluticasone propionate 880  $\mu\text{g}$  twice per day (with unrestricted diet), for 6 weeks. Histological remission after switching therapy was assessed as a secondary endpoint. Efficacy and safety analyses were done in the intention-to-treat (ITT) population. This trial is registered on [ClinicalTrials.gov](https://clinicaltrials.gov), NCT02778867, and is completed.

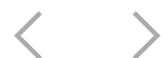
## Findings

Between May 23, 2016, and March 6, 2019, 129 patients (70 [54%] men and 59 [46%] women; mean age 37.0 years [SD 10.3]) were enrolled, randomly assigned to 1FED (n=67) or 6FED (n=62), and included in the ITT population. At 6 weeks, 25 (40%) of 62 patients in the 6FED group had histological remission compared with 23 (34%) of 67 in the 1FED group (difference 6% [95% CI -11 to 23];  $p=0.58$ ). We found no significant difference between the groups at stricter thresholds for partial remission ( $\leq 10$  eos/hpf, difference 7% [-9 to 24],  $p=0.46$ ;  $\leq 6$  eos/hpf, 14% [-0 to 29],  $p=0.069$ ); the proportion with complete remission was significantly higher in the 6FED group than in the 1FED group (difference 13% [2 to 25];  $p=0.031$ ). Peak eosinophil counts decreased in both groups (geometric mean ratio 0.72 [0.43 to 1.20];  $p=0.21$ ). For 6FED versus 1FED, mean changes from baseline in EoEHSS (-0.23 vs -0.15; difference -0.08 [-0.21 to 0.05];  $p=0.23$ ), EREFS (-1.0 vs -0.6; difference -0.4 [-1.1 to 0.3];  $p=0.28$ ), and EEsAI (-8.2 vs -3.0; difference -5.2 [-11.2 to 0.8];  $p=0.091$ ) were not significantly different. Changes in quality-of-life scores were small and similar between the groups. No adverse event was observed in more than 5% of patients in either diet group. For patients without histological response to 1FED who proceeded to 6FED, nine (43%) of 21 reached histological remission; for patients without histological response to 6FED who proceeded to fluticasone propionate, nine (82%) of 11 reached histological remission.

## Interpretation

Histological remission rates and improvements in histological and endoscopic features were similar after 1FED and 6FED in adults with eosinophilic oesophagitis. 6FED had efficacy in just less than half of 1FED non-responders and steroids had efficacy in most 6FED non-responders. Our findings indicate that eliminating animal milk alone is an acceptable initial dietary therapy for eosinophilic oesophagitis.

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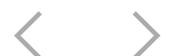
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