

primary studies - published RCT

## **Ataluren for the treatment of nonsense-mutation cystic fibrosis: a randomised, double-blind, placebo-controlled phase 3 trial.**

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### **Study design (if review, criteria of inclusion for studies)**

Randomized controlled trial

### **Participants**

79 CF patients (median age 19.6 years; 9.2-36.9) with a positive Glucose Breath Test (GBT)

### **Interventions**

Rifaximin 1200 mg for 14 days or no treatment.

### **Outcome measures**

Questionnaire and GBT were repeated 1 month after the end of treatment or 45 days after the first negative GBT. BMI, SDS-BMI, serum albumin levels (p

### **Main results**

Out of 79 patients, 25 were affected by SIBO (31.6%) with a significant correlation with lower BMI, SDS-BMI ( $p < 0.05$ ) and serum albumin levels ( $p < 0.05$ ), independently from pancreas insufficiency. Twenty-three patients took part in the randomized trial, 13 patients (56.5%) in rifaximin group and 10 patients (43.5%) in control group. Eradication rate of SIBO was 9/10 (90%) in rifaximin group and 2/6 (33.3%) in control group ( $p < 0.05$ ). In the rifaximin group, gastrointestinal symptom improvement was observed in 4/5 patients aged  $\leq 14$  years and in 0/5 patients aged  $> 14$  years (p

### **Authors' conclusions**

CF patients show a high prevalence of SIBO, related to a poorer nutritional status. Rifaximin therapy is well tolerated and the results are promising in terms of efficacy in eradicating small intestinal bacterial overgrowth in CF.

[http://dx.doi.org/10.1016/S2213-2600\(14\)70100-6](http://dx.doi.org/10.1016/S2213-2600(14)70100-6)

### **See also**

Lancet Respir Med. 2014 May 15. pii: S2213-2600(14)70100-6. doi: 10.1016/S2213-2600(14)70100-6.

### **Keywords**

Rifaximin; other anti-bacterial agents; Anti-Bacterial Agents; pharmacological\_intervention;