

primary studies - published RCT

## **A randomized double blind, placebo controlled phase 2 trial of BIIL 284 BS (an LTB receptor antagonist) for the treatment of lung disease in children and adults with cystic fibrosis.**

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

Randomized, double-blind, placebo-controlled study

### **Participants**

CF patients aged  $\geq 6$  years with mild to moderate lung disease. 420 (155 children, 265 adults) of the planned 600 patients were randomized

### **Interventions**

Leukotriene B4 (LTB4)-receptor antagonist BIIL 284 BS vs placebo once daily for 24 weeks.

### **Outcome measures**

Co-primary endpoints were change in FEV1 and incidence of pulmonary exacerbation.

### **Main results**

After 420 (155 children, 265 adults) of the planned 600 patients were randomized, the trial was terminated after a planned interim analysis revealed a significant increase in pulmonary related serious adverse events (SAEs) in adults receiving BIIL 284 BS. Final analysis revealed SAEs in 36.1% of adults receiving BIIL 284 BS vs. 21.2% receiving placebo ( $p=0.007$ ), and in 29.6% of children receiving BIIL 284 BS vs. 22.9% receiving placebo ( $p=0.348$ ). In adults, the incidence of protocol-defined pulmonary exacerbation was greater in those receiving BIIL 284 BS than in those receiving placebo (33.1% vs. 18.2% respectively;  $p=0.005$ ). In children, the incidence of protocol-defined pulmonary exacerbation was 19.8% in the BIIL 284 BS arm, and 25.7% in the placebo arm ( $p=0.38$ ).

### **Authors' conclusions**

While the cause of increased SAEs and exacerbations due to BIIL 284 BS is unknown, the outcome of this trial provides a cautionary tale for the administration of potent anti-inflammatory compounds to individuals with chronic infections, as the potential to significantly suppress the inflammatory response may increase the risk of infection-related adverse events.

<http://dx.doi.org/10.1016/j.jcf.2013.12.009>

### **See also**

J Cyst Fibros. 2014 Jan 16. pii: S1569-1993(13)00238-5. doi: 10.1016/j.jcf.2013.12.009.

### **Keywords**

Amelubant; Leukotriene Antagonists; pharmacological\_intervention; Respiratory Tract Diseases;