*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 >/=6years 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 24weeks.

### 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.

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### 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;