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.

Code: PM24440167 **Year:** 2014 **Date:** 2014 **Author:** Konstan MW

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.

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;