primary studies - published RCT

Efficacy, safety and effect on biomarkers of AZD9668 in cystic fibrosis

Code: PM22267768 **Year:** 2012 **Date:** 2012 **Author:** Elborn JS

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

Randomised, double-blind, placebo-controlled study.

Participants

56 CF patients

Interventions

The neutrophil elastase inhibitor AZD9668 (60 mg twice daily orally for 4 weeks). 56 patients were randomised, of which 27 received AZD9668.

Outcome measures

Primary outcome measures were sputum neutrophil count, lung function, 24-h sputum weight, BronkoTest(registered trademark) diary card data and health-related quality-of-life (revised cystic fibrosis quality-of-life questionnaire). Secondary end-points included sputum neutrophil elastase activity, inflammatory biomarkers in sputum and blood, urine and plasma desmosine (an elastin degradation marker), AZD9668 levels and safety parameters (adverse events, routine haematology, biochemistry, electrocardiogram and sputum bacteriology).

Main results

There was no effect for AZD9668 on sputum neutrophil counts, neutrophil elastase activity, lung function or clinical outcomes, including quality of life. In the AZD9668 group, there was a trend towards reduction in sputum inflammatory biomarkers with statistically significant changes in interleukin-6, RANTES and urinary desmosine. The pattern of adverse events was similar between groups. Consistent reductions in sputum inflammatory biomarkers were seen in the AZD9668 group, and reduction in urinary desmosine suggests that AZD9668 impacts elastin cleavage by neutrophil elastase.

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See also

European Respiratory Journal

Keywords

Adult; Aged; Anti-Inflammatory Agents; AZD9668; Child; Oral; pharmacological_intervention; Anti-Inflammatory Agents - excl Steroids;