

primary studies - published RCT

## Lumacaftor/ivacaftor in cystic fibrosis: effects on glucose metabolism and insulin secretion.

Code: PM33586024

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Author: Colombo C

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

randomized trial

### Participants

87 patients with cystic fibrosis were admitted to hospital with an acute exacerbation of pulmonary symptoms associated with isolation of *Pseudomonas aeruginosa* from sputum. The two therapy groups were comparable in all aspects.

### Interventions

intravenously administered ceftazidime (250 mg/kg/day) and amikacin (33 mg/kg/day) alone or with inhaled amikacin (100 mg twice a day). Other aspects of the 2-week treatment were constant.

### Outcome measures

eradication of *P. aeruginosa*, clinical, radiologic, laboratory, and pulmonary function measurements, toxicity and adverse effect.

### Main results

At the completion of therapy, the addition of aerosolized amikacin produced temporary eradication of *P. aeruginosa* in 70% of the patients, compared with 41% in the intravenous therapy only group ( $P$  less than 0.02). Suppression of *P. aeruginosa* in sputum cultures was correlated with the amikacin sputum concentrations. However, both regimens resulted in similar improvements in clinical, radiologic, laboratory, and pulmonary function measurements, and within 4 to 6 weeks most patients were recolonized with *P. aeruginosa*. There was no serious toxicity or adverse effect.

### Authors' conclusions

In patients with cystic fibrosis, the addition of aerosol aminoglycoside to systemic antipseudomonal combination therapy is not clinically beneficial.

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### See also

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### Keywords

Adolescent; Adult; Amikacin; Anti-Bacterial Agents; Bacterial Infections; Ceftazidime; Child; Combined Modality Therapy; Infection; Inhalation OR nebulised; Intravenous; pharmacological\_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation; Aminoglycosides; Cephalosporins;