

primary studies - published RCT

# Maternal and fetal outcomes following elexacaftor-tezacaftor-ivacaftor use during pregnancy and lactation.

**Code:** PM33762125

**Year:** 2021 **Date:** 1987

**Author:** Taylor-Cousar JL

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

randomized, double-blind trial

## Participants

85 patients with cystic fibrosis who were experiencing an acute infectious exacerbation. 3 patients were dropped from the study within 4 days of enrollment for reasons unrelated to drug administration.

## Interventions

50 or 75 mg of ceftazidime per kg (body weight) per dose administered intravenously every 8 h for 14 days. The total daily dose of ceftazidime administered was restricted by protocol design and was independent of the body weight of the patient. Thus, for datum analysis, patients were separated into three ceftazidime dosage groups (denoted as range of milligrams per kilogram per dose): group 1, 22 to 44.5; group 2, 46.3 to 56.6; and group 3, 66.7 to 80.6.

## Outcome measures

sputum colony counts, bacterial resistance, MIC, clinical outcome. Adverse events

## Main results

Ceftazidime monotherapy had no effect on sputum colony counts for any *Pseudomonas cepacia* isolate. In contrast, a substantial reduction in *Pseudomonas aeruginosa* sputum colony counts was observed, and from 19 to 31% of isolates were suppressed greater than or equal to 10(5) CFU/ml after 14 days of therapy. Bacterial resistance in vitro was not observed, although a trend for increasing ceftazidime MICs was observed for group 1 patients (P less than 0.05). Overall, clinical response appeared independent of drug dose, and no relationship could be identified between the reduction in *P. aeruginosa* sputum colony counts and clinical outcome. Adverse effects of ceftazidime were mild and transient, necessitating drug discontinuation in one patient.

## Authors' conclusions

These data suggest that the clinical response to ceftazidime in patients with cystic fibrosis may be maximal with 50 mg/kg per dose (150 mg/kg per day) up to a total daily dose of 6 g.

<http://dx.doi.org/10.1016/j.jcf.2021.03.006>

## See also

J Cyst Fibros. 2021 May;20(3):402-406. doi: 10.1016/j.jcf.2021.03.006. Epub 2021 Mar 22.

## Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Ceftazidime; Child; Infection; Inpatient; pharmacological\_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation; Intravenous; Cephalosporins;