primary studies - published RCT

Therapeutic efficacy and safety of amitriptyline in patients with cystic fibrosis.

Code: PM19590194 **Year:** 2009 **Date:** 2009 **Author:** Riethmüller J

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

randomised, double-blinded, placebo-controlled, cross-over pilot study

Participants

4 adult CF patients. Subsequently in a phase II study 19 adult CF patients

Interventions

4 adult CF patients received 37.5 mg of amitriptyline or placebo twice daily for 14 days. Subsequently in a phase II study 19 adult CF patients were randomly allocated to three treatment groups receiving amitriptyline once daily for 28 days at doses of 25 mg (n=7), 50 mg (n=8), or 75 mg (n=8) or placebo (n=13).

Outcome measures

The primary outcome was the difference of forced expiratory volume in 1 sec (FEV(1)) at day 14 between amitriptyline and placebo.

Main results

Primary endpoint measures improved significantly in three of four patients in the pilot study after amitriptyline treatment vs placebo (relative FEV(1): 14.7+/-5%; p = 0.006) and in the 25 mg treatment group of the phase II study (relative FEV(1): 4.0+/-7%; p = 0.048). Amitriptyline was well tolerated in both studies and 96% of the patients completed the studies.

Authors' conclusions

Amitriptyline as a novel therapeutic option in patients with CF is safe and seems to be efficacious.

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See also

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Keywords

Adult; Amitriptyline; Anti-Bacterial Agents; Anti-Inflammatory Agents; Bacterial Infections; Infection; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Anti-Inflammatory Agents - excl Steroids;