primary studies - published RCT

Therapy of CF-patients with amitriptyline and placebo--a randomised, double-blind, placebo-controlled phase IIb multicenter, cohort-study.

Code: PM23572075 **Year:** 2013 **Date:** 2013 **Author:** Nahrlich L

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

phase IIb randomised, double-blind, placebo-controlled study

Participants

CF patients

Interventions

patients were treated with 25 mg/d amitriptyline twice daily for 28 days. The placebo consisted of 19 patients and was also treated twice per day.

Outcome measures

The primary endpoint was the change in lung function in the intention-to-treat (ITT) population. Secondary endpoints were ceramide levels in epithelial cells and safety.

Main results

After treatment, forced expiratory volume in 1 sec predicted (FEV1) increased 6.3 +/- 11.5% (p=0.08) in the ITT population (36 of 40 CF patients) and 8.5 +/- 10% (p=0.013) in the per protocol (PP) population (29 of 40 patients). Ceramide levels decreased in nasal epithelial cells after amitriptyline treatment. Amitriptyline had no severe and only mild and mostly transient adverse effects, i.e. xerostomia and tiredness.

Authors' conclusions

Amitriptyline is safe in CF-patients, increases FEV1 and reduces ceramide in lung cells of CF patients.

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See also

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Keywords

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