

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:** 2016

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

Pilot, double-blind, randomized controlled, parallel-group, 1:1 trial

### **Participants**

Stable CF patients older than 6 years of age and with a FEV1pred. >40%

### **Interventions**

Patients were randomized to one of the treatment arms, Hypertonic saline (HS) or HS+hyaluronic acid (HA), to be administered twice a day at home.

### **Outcome measures**

Clinical data, inflammatory markers (IL-1beta, IL-6, IL-8, IL-10, TNF-alpha, VEGF) in sputum, and judgments on the tolerability and pleasantness were collected at the beginning and after 28 days.

### **Main results**

HA+HS had no significant effect on inflammatory markers versus HS alone, as shown by broad confidence intervals. In the HS+HA group, the highest decrement from baseline values was observed for IL-1beta (-58.8%) followed by VEGF (-49.9%), whereas in the HS group a significant increment of IL-10 levels (+83.0%;  $p = 0.011$ ) was the only significant finding. Prevalence of unfavorable scores was 36.8% in HA+HS versus 55% in HS group ( $p = 0.207$ ); no significant differences were detected in the prevalence of moderate/severe symptoms of cough, saltiness, and throat irritation in pulmonary functions tests after 28 days.

### **Authors' conclusions**

HS+HA administration in CF patients does not show any significant effects on lung inflammation and function as compared to HS alone.

<http://dx.doi.org/10.1159/000350071>

### **See also**

Cell Physiol Biochem. 2013;31(4-5):505-12. doi: 10.1159/000350071. Epub 2013 Apr 2.

### **Keywords**

Adolescent; Child; hyaluronic acid; hydration; Hypertonic Solutions; Inhalation OR nebulised; pharmacological\_intervention; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents;