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primary studies - published RCT

## **A double-blind, randomized study of sodium cromoglycate versus placebo in patients with cystic fibrosis and bronchial hyperreactivity.**

**Code:** PM2107242

**Year:** 1990 **Date:** 1990

**Author:** Sivan Y

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

long-term, double-blind, placebo-controlled, crossover study

### **Participants**

14 patients with CF and without asthma (aged 7 to 29 years) and with bronchial hyperreactivity entered the study.

### **Interventions**

Each patient received 8 weeks of 1% SCG nebulizer solution three to four times daily and 8 weeks of placebo. Seven patients received the treatment in the order SCG/placebo and seven patients in the reverse order.

### **Outcome measures**

Evaluation of SCG effect was performed every 4 to 8 weeks by (1) clinical assessment of symptoms, (2) clinician and patient/parent opinion, (3) pulmonary function tests, and (4) methacholine provocation tests. After two patients were withdrawn for lack of cooperation, the results were evaluated for treatment effect (SCG versus placebo), period effect (whether SCG was administered first or last), or combination of both.

### **Main results**

No significant difference was found for these parameters for the clinical assessment of symptoms, the patient/parent and clinician opinion, their subjective preferences, the metacholine challenges, or the pulmonary function tests

### **Authors' conclusions**

The study did not demonstrate any benefit from the use of SCG in patients with CF and with bronchial hyperreactivity and does not support the routine use of SCG in patients with CF.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/370/CN-00066370/frame.html>

### **See also**

J Allergy Clin Immunol. 1990 Mar;85(3):649-54.

### **Keywords**

Adolescent; Adult; Child; Cromolyn Sodium; Methacholine; pharmacological\_intervention; placebo; Respiratory System Agents;