

primary studies - published RCT

## **A phase II, double-blind, randomized, placebo-controlled clinical trial of tgAAVCF using maxillary sinus delivery in patients with cystic fibrosis with antrostomies.**

**Code:** PM12162817

**Year:** 2002 **Date:** 2005

**Author:** Wagner JA

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

pilot study. randomised double-blind placebo-controlled crossover study

### **Participants**

1st part: 8 CF patients + 8 healthy controls. 2nd part: 10 CF patients (5 females)

### **Interventions**

oral L-arginine was given in a single dose of 200 mg x kg<sup>-1</sup> body weight to healthy controls and CF patients. Subsequently, the same L-arginine dose was given to CF patients t.i.d. for 6 weeks

### **Outcome measures**

L-arginine in plasma and sputum, eNO, FEV1

### **Main results**

A single dose of oral L-arginine resulted in a 5.5-fold increase of L-arginine in plasma and a 1.3-fold increase of L-arginine in sputum after 2 h. Maximum eNO, within 3 h of L-arginine intake, increased significantly in both CF patients (5.4+/-2.1 ppb versus 8.3+/-3.5 ppb) and controls (18.0+/-8.1 ppb versus 26.4+/-12.3 ppb). Supplementation of L-arginine for 6 weeks resulted in a sustained increase in eNO compared to placebo (9.7+/-5.7 ppb versus 6.3+/-3.1 ppb). An effect of L-arginine supplementation on forced expiratory volume in one second was not observed.

### **Authors' conclusions**

These data indicate that airway nitric oxide formation in cystic fibrosis patients can be augmented with oral L-arginine supplementation.

<http://dx.doi.org/10.1089/104303402760128577>

### **See also**

Hum Gene Ther. 2002 Jul 20;13(11):1349-59.

### **Keywords**

Adolescent; Adult; Arginine; Drug Administration Schedule; non pharmacological intervention - diet; Oral; placebo; Supplementation; Amino Acids; Proteins;