

---

primary studies - published RCT

## A phase II study on safety and efficacy of high-dose N-acetylcysteine in patients with cystic fibrosis.

**Code:** PM19666395

**Year:** 2009 **Date:** 2009

**Author:** Dauletbaev N

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

single-centre, randomised, double-blinded, placebo-controlled phase II clinical study to test safety and efficacy

### Participants

21 patients (DeltaF508 homo/heterozygous, FEV1>40% pred.) were included in the study

### Interventions

12-week therapy with low-dose (700 mg/daily) or high-dose (2800 mg/daily) of NAC. After a 3-weeks placebo run-in phase, 11 patients received low-dose NAC, and 10 patients received high-dose NAC.

### Outcome measures

Outcomes included safety and clinical parameters, inflammatory (total leukocyte numbers, cell differentials, TNF-alpha, IL-8) measures in induced sputum, and concentrations of extracellular glutathione in induced sputum and blood

### Main results

High-dose NAC was a well-tolerated and safe medication. High-dose NAC did not alter clinical or inflammatory parameters. However, extracellular glutathione in induced sputum tended to increase on high-dose NAC.

### Authors' conclusions

High-dose NAC is a well-tolerated and safe medication for a prolonged therapy of patients with CF with a potential to increase extracellular glutathione in CF airways.

<http://dx.doi.org/10.1186/2047-783X-14-8-352>

### See also

Eur J Med Res. 2009 Aug 12;14(8):352-8.

### Keywords

Acetylcysteine; Adult; Antioxidants; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Glutathione; High-Dose; N Acetylcysteine; pharmacological\_intervention; thiols; Low-Dose; Respiratory System Agents; Nacystelyn;