

primary studies - published RCT

20 years of the Montreal Cystic Fibrosis Related Diabetes Screening Cohort: key insights.

Code: PM40368427

Year: 2025 **Date:** 1989

Author: Alexandre-Heymann L

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

Randomized, double-blind, placebo-controlled, cross-over study design. 2 periods of 3 months receiving either active drug or placebo. Single centre in Denmark. All participants received intravenous antibiotics routinely on a 3-monthly basis, once before starting the trial and again at the mid-point of the trial. Not ITT as 21 participants were excluded from the final analysis.

Participants

52 participants with CF, with 31 (17 males) completing it. All were chronically infected with *Pseudomonas aeruginosa*. Mean age 15 years (range 7 - 33). Lung function ranged from severely impaired to normal. All pre-trial treatments continued during the trial.

Interventions

Oral NAC 200 mg tid (< 30kg), oral NAC 400 mg BD (> 30kg), or placebo (bicarbonate tablets).

Outcome measures

Monthly 'subjective score', body weight, sputum bacteriology and PFTs (FVC, FEV1, PEF). Blood test for WBC, ESR and antibodies to *Staphylococcal aureus*, *Haemophilus influenzae* and *Pseudomonas aeruginosa* at the start of the trial and at the end of each 3-m

Main results

31 patients completed the study. No significant differences in lung function or subjective clinical scores were seen between NAC and placebo for the study group as a whole. Patients with peak expiratory flow rate (PEFR) below 70% of predicted normal values showed a satisfactory significant increase in PEFR, forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) during NAC treatment. No effect of NAC on ciliary activity was observed.

<http://dx.doi.org/10.1183/16000617.0220-2024>

See also

Eur Respir Rev. 2025 May 14;34(176):240220. doi: 10.1183/16000617.0220-2024. Print 2025 Apr.

Keywords

Acetylcysteine; Adolescent; Adult; Bacterial Infections; Child; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Infection; N Acetylcysteine; pharmacological_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Infections; Oral; Tablets; thiols; Respiratory System Agents; Nacystelyn; Respiratory Tract Diseases;