primary studies - published RCT

Recombinant human DNase nebulisation in children with cystic fibrosis: before bedtime or after waking up?.

Code: PM17596273 **Year:** 2007 **Date:** 2007 **Author:** van der Giessen LJ

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

randomised, double-blind, double-dummy, crossover study group

Participants

The inclusion criteria were as follows: 1) CF, 2) stable clinical condition and 3) rhDNase maintenance therapy. A total of 24 patients completed the study. The mean (range) age of the patients was 13 (6-19) yrs.

Interventions

Patients in group I inhaled rhDNase before bedtime and a placebo after waking up in weeks 1-2. The protocol was reversed during weeks 3-4. In group II patients performed the reverse of this sequence. Patients continued with their daily routine sputum expectoration.

Outcome measures

The primary end-point was classified as the maximal instantaneous forced flow when 25% of the forced vital capacity remained to be exhaled (MEF(25%)). Pulmonary functions tests were performed on days 0, 7, 14, 21 and 28. At 1, 2, 3 and 4 weeks arterial oxygen saturation and cough frequency were measured during the night.

Main results

MEF(25%), taken to be the primary end-point, did not show a significant difference between nebulisation of rhDNase before bedtime compared with when taken after waking up. Nocturnal cough, oxygen saturation, and other secondary end-points were not significantly different between the two study periods.

Authors' conclusions

the present study found that it is equally effective and safe to nebulise recombinant human deoxyribonuclease before bedtime compared with when performed after waking up in children with cystic fibrosis, who are on maintenance treatment with recombinant human deoxyribonuclease.

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See also

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Keywords

Adolescent; Child; Deoxyribonuclease; Drug Administration Schedule; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; placebo; Recombinant Proteins; Respiratory System Agents; Dornase alpha; Pulmozyme;