HTA - - Health Technology Assessment Report

Comparison of biosimilar Tigerase and Pulmozyme in long-term symptomatic therapy of patients with cystic fibrosis and severe pulmonary impairment (subgroup analysis of a Phase III randomized open-label clinical trial (NCT04468100)).

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List of included studies (3)

Elkins et al 2006: Level II intervention evidence Subbarao et al 2007 and Dellon et al 2008: Level IV intervention evidence

Participants

Elkins (2006): n= 164 (6 years of age or older); Subbarao (2007): n= 13 (infants 3 months or older); Dellon (2008): n= 8 infants (4 months to 3 years old) and 7 preschoolers (4 years to 7 years)

Interventions

Elkins (2006): subjects were randomised to the experimental group, inhaling 4 ml of 7 per-cent hypertonic saline, or the control group, inhaling 4 ml of 0.9 percent saline, twice daily for 48 weeks. Both groups were treated with a bronchodilator before inhalation. Subjects continued their normal course of treatment. Subbarao (2007): Infants were sedated orally with chloral hydrate (60â€“100 mg/kg). A sequential treatment regimen consisting of a throat swab for microbiologic assessment, a baseline assessment of pulmonary function, administration of a bronchodilator, a second assessment of pulmonary function, hypertonic saline administration (4 ml of 7% saline was administered for 15 min via infant face mask (Pari baby) attached to a Pari LC Star nebulizer and a Pari Ultra Neb compressor) and a third assessment of pulmonary function. Dellon (2008): administration of a bronchodilator, baseline pulmonary function assessment, treatment with normal saline, a second pulmonary function assessment, treatment with hypertonic saline (3% or 7% saline in separate studt visits), then a third pulmonary function assessment.

Outcome measures

Elkins (2006): primary outcome = change in lung function (FEV1, FVC, FEF25-75); secondary outcomes = frequency of pulmonary exacerbations, antibiotic use for exacerbations, absenteeism from work or school. Subbarao (2007): primary oucome = safety and tolerability; secondary ouctomes = effect of a single inhalation on the yield of throat swabs to detect bacterial pathogens in CF infants. Dellon (2008): primary outcome = safety and tolerability

Main results

The studies assessed here show that hypertonic saline has minimal side effects in CF patients and appears to be safe for usage in infants and children. A long term, blinded trial showed that while there was no difference in lung function over the study period there were improvements in several important secondary outcomes, such as lung exacerbations and increased quality of life.

Authors' conclusions

- Given the low cost and safety of hypertonic saline treatment it seems to be a moderately effective additional therapy for CF patients. - Further studies are needed to assess the potential hypertonic saline induced changes to lung function that may either be beneficial or detrimental and whether this has an impact on quality of life and survival.

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See also

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Keywords

hydration; Hypertonic Solutions; pharmacological_intervention; Inhalation OR nebulised; Oral; Respiratory System Agents;