primary studies - published RCT

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)).

Code: PM34941914 **Year:** 2021 **Date:** **Author:** Amelina EL

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

Post hoc sub-analysis of a larger comparative study (phase III open label, prospective, multi-centre, randomized study)

Participants

A subgroup of 46 severe pulmonary impairment patients with baseline FEV1 level 40-60% of predicted (23 patients in each treatment group) out of 100 patients registered in the study phase III open label, prospective, multi-center, randomized study

Interventions

A generic version of recombinant human DNase Tigerase® and the only comparable drug, Pulmozyme®.

Outcome measures

Efficacy endpoints (FEV1, FVC, number and time of exacerbations, body weight, St.George's Respiratory Questionnaire) as well as safety parameters (AEs, SAEs, anti-drug antibody) within 24 treatment weeks.

Main results

All outcomes were comparable among the studied groups. In the efficacy dataset, the similar mean FEV1 and mean FVC changes for 24 weeks of both treatment groups were observed. The groups were also comparable in safety, all the secondary efficacy parameters and immunogenicity.

Authors' conclusions

The findings from this study support the clinical Tigerase® biosimilarity to Pulmozyme® administered in CF patients with severe impairment of pulmonary function.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Deoxyribonuclease; Airway clearance drugs -expectorants-mucolytic- mucociliary-; Infant; Infection; Inhalation OR nebulised; pharmacological_intervention; Pneumonia; Respiratory Tract Infections; colonization; Staphylococcus aureus; Respiratory System Agents; Respiratory Tract Diseases; Dornase alpha; Pulmozyme; tigersae;