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Title: Long-term efficacy and safety of tobramycin 300mg/4mL nebuliser solution in patients with cystic fibrosis and chronic Pseudomonas aeruginosa infection

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Body: Introduction: Inhaled tobramycin is considered as standard of care for the management of chronic Pseudomonas aeruginosa (Pa) infection in patients (pts) with cystic fibrosis (CF). Objectives: The long-term efficacy and safety of tobramycin 300mg/4mL nebuliser solution (TNS4: Bramitob®, Chiesi FarmaceuticiS.p.A.) administered over 56 weeks (seven 28-day on/off cycles) was assessed in CF pts chronically infected with Pa. Methods: A total of 324 CF pts aged ≥ 6 years with baseline 1-second forced expiratory volume (FEV_1) 40-80% predicted were randomized in an initial 8-week, open-label trial (Core) to receive TNS4 or tobramycin 300mg/5mL (TNS5, Tobi®, Novartis) using PARI Turbo Boy N compressor and PARI LC Plus nebuliser. 209 pts (of which 100 received TNS4 in the Core) continued for an additional 48-week, single-arm extension phase with TNS4 only (Ext). FEV_1% predicted and Pa bacterial load in sputum were measured during 14 study visits. Safety was assessed through monitoring of adverse events and audiometry. Results: Non-inferiority in terms of FEV_1 % predicted between TNS4 and TNS5 was demonstrated in the Core (mean changes from baseline 7.1% and 7.6%, respectively). After 56-week treatment with TNS4, the mean change from baseline in FEV_1% predicted was 5.7% [95% CI: 2.8;8.6]. Reduction in log_{10}CFU/g Pa bacterial load was -1.13 [95% CI: -1.58;-0.68]. No remarkable safety findings were detected. Conclusions: TNS4 demonstrated a sustained and significant improvement in lung function over a 56-week period and a reduction in Pa density in sputum. TNS4 was safe and well tolerated.
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