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Title: The efficacy and safety of inhaled flumucil-antibiotic-IT in the treatment of exacerbations of COPD and chronic bronchitis with bronchiectasis

Dr. Valentina 24532 Kapustina kapustina@pochta.ru MD ¹ and Prof. Svetlana 24533 Ovcharenko svetfkk@mail.ru MD ¹. ¹ Faculty Therapy No.1, I.M. SechenovFirst Moscow State Medical University, Moscow, Russian Federation .

Body: Introduction: In severe exacerbations of COPD and chronic bronchitis accompanied by difficult expectorated purulent sputum there is a need in both antibiotic and mucolytic treatment. Aims: To investigate the efficacy and safety of an original combination drug - inhaled Thiamphenicol Glycinate Acetylcysteinate (Fluimucil-antibiotic-IT) 500 mg daily. Methods: 15 patients with acute exacerbation of COPD (phenotype of airways disease) and 10 patients with acute exacerbation of chronic bronchitis with bronchiectasis were recruited (60% male, with mean age of 59.4±16.0 and %FEV1 64.3±11.5%). Nebulized Fluimucil-antibiotic-IT was administrated 250 mg BID for 6 days. At baseline and after 6 days respiratory symptoms severity, inflammation markers, sputum culture were assessed and adverse events were collected. Results: After 6 days of treatment it was noted decrease the severity of sputum production (4 vs 1.5, p<0.05) and cough (2<1, p=0.6), decrease of C-reactive protein (15.0 vs 6.2 mg/dl, p<0.05) and leukocytes sputum level (50 vs 20 in sight, p<0.05). Fluimucil-antibiotic-IT had shown the wide spectrum of antimicrobial activity: the disappearance of pathogenic organisms (Streptococcus species / Haemophilus influenzae / Moraxella catarrhalis) in 20 patients and also disappearance of Pseudomonas aeruginosa in sputum culture in 2 patients. No significant differences in lung function were found. Side effects of the treatment have not been reported. Conclusions: Fluimucil-antibiotic-IT is effective and safe combination treatment of COPD and chronic bronchitis exacerbations.