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O-A-004

OMALIZUMAB IMPROVES QUALITY OF LIFE AND ASTHMA CONTROL IN CHINESE PATIENTS WITH MODERATE-TO-SEVERE ASTHMA: A RANDOMIZED PHASE III STUDY

LI J[1], KANG J[2], CANVIN J[3], WANG C[4], ZHONG Nanshan[1], YANG J[5], HUMPHRIES M[5]
[1]State Key Laboratory of Respiratory Disease, The First Affiliated Hospital, Guangzhou Medical University, Guangzhou, China, [2]Institute of Respiratory Disease, First Hospital of China Medical University, Shenyang, China, [3]Novartis Pharmaceuticals UK Ltd, Horsham, UK, [4]Department of Respiratory Disease, Xinqiao Hospital, Third Military Medical University, Chongqing, China, [5]Primary Care, Beijing Novartis Pharma Co. Ltd, China

Introduction: Omalizumab, an anti-IgE monoclonal antibody, has been found to be effective and safe in the treatment of patients of different ethnicities with moderate-to-severe allergic asthma. We report here the effect of omalizumab on the quality of life, asthma control and safety in Chinese patients with moderate to severe allergic asthma.
Methods: This was a randomized, double blind, parallel group, placebo controlled, phase III study to assess the quality of life, asthma control and safety of 24 weeks of omalizumab therapy in Chinese patients, aged 18–75 years, with moderate-to-severe persistent allergic asthma. Asthma Quality of Life Questionnaire (AQLQ) and Asthma Control Questionnaire (ACQ) scores were assessed at baseline and at week 24. Asthma exacerbation rates were also analysed.
Results: Among the 608 patients included in the full analysis set, at week 24 a higher proportion of patients treated with omalizumab (n = 306), vs. placebo (n = 302), achieved clinically relevant improvements in AQLQ (58.2% vs. 39.3% [analysed n = 182 vs. 178]: $p < 0.001$; change from baseline [ΔBL] = 0.51 vs. 0.10) and ACQ (49.5% vs. 35.5% [analysed n = 210 vs. 211]: $p = 0.003$; ΔBL = −0.51 vs. −0.34) scores. Although not powered to study differences in exacerbation rates ($p = 0.097$), exacerbations in winter months were less frequent in the omalizumab group vs. placebo (2 vs.21). Adverse event and serious adverse event rates were comparable in both groups. One death from asthma exacerbation occurred in the omalizumab group.
Conclusions: Omalizumab improves quality of life and asthma control in Chinese patients with moderate-to-severe persistent allergic asthma with a good safety profile.

O-A-005

A NOVEL THROMBOXANE A2 RECEPTOR INHIBITOR, SERATRODAST SHOWS GREATER IMPROVEMENT IN PEAK EXPIRATORY FLOW, EXPECTORATION SCORE, SPUTUM EOSINOPHIL CATIONIC PROTEIN AND ALBUMIN LEVELS AS COMPARED TO MONTELUKAST IN A DOUBLE BLIND COMPARATIVE CLINICAL TRIAL

DEWAN B, NAVALE S, SHAH D
Zuventus Healthcare Limited, Chandivali Mumbai, India

Background: Thromboxane A2 (TXA2) has shown to play an important role in the pathogenesis of asthma. Various international guidelines recommend controller therapy for mild to moderate persistent asthma. Seratrodast, a specific TXA2 receptor antagonist, given orally, has demonstrated consistent benefit in controlling symptoms of asthma. Therefore, we designed a randomized, double blind, double dummy, multi-centre, parallel group study with non inferiority design to assess the efficacy, safety and tolerability of seratrodast versus montelukast, a leukotriene receptor antagonist, in controlling mild to moderate asthma in adult patients.
Methods: Patients (n = 205) with mild to moderate asthma continuing on the lowest dose of inhaled corticosteroid were recruited from 3 different centers across India. Patients were randomly assigned to receive either seratrodast 80 mg (n = 103) or montelukast 10 mg (n = 102) once daily for 28 days. The objective was to compare the treatments in terms of improvement from the baseline values, as per the changes in asthma symptom score (wheezing, shortness of breath, expectoration, cough and chest tightness), lung function parameters (PEF, FVC and FEV1), sputum and mucociliary parameters [fucose, eosinophil cationic protein (ECP) and albumin].
Results: Seratrodast and montelukast showed improvement in the clinical parameters of asthma as well as in the lung function tests and sputum parameters from baseline. Both the treatments significantly increased mean values of PEF, FVC and FEV1 from the baseline after a 4 week treatment but seratrodast produced significantly higher improvement in PEF (0.416 L/s, $P < 0.05$). Moreover, there was significantly higher reduction in expectoration score, sputum concentrations of ECP and albumin in seratrodast group ($P < 0.05$), signifying improvement in asthma condition. The two treatment groups had similar tolerability profiles. Mild increase in hepatic enzymes was seen in both the groups with no significant difference in incidence (n = 31 in montelukast and n = 37 in seratrodast group); no serious adverse events were reported during the study.
Conclusions: Seratrodast, a TXA2 receptor antagonist, was found to be better in the improvement of PEF, expectoration score, ECP and albumin level as compared to montelukast justifying preference of seratrodast as a controller medication in mild to moderate asthma.
Trial Registration: Clinical Trial Registry of India: CTRI/2013/03/003504 http://ctri.nic.in/Clinicaltrials/rmaindet.php?trialid=3253&EncHid=28792.92343&modid=1&compid=19
Key words: Thromboxane A2 receptor antagonist, asthma, seratrodast, montelukast, peak expiratory flow (PEF), eosinophil cationic protein (ECP), albumin.