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A randomized, double-blind, comparative, phase III, non-inferiority clinical trial between triamcinolone acetonide nasal spray (TAA) and fluticasone propionate nasal spray (FP) in adults suffering from perennial allergic rhinitis (PAR) in Russia: Secondary outcomes result

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A randomized, double-blind, parallel-group, multicenter, phase III, prospective, non-inferiority clinical trial (NCT 03317015) sponsored by Sanofi compared triamcinolone acetonide (TAA) nasal spray (220 μg/d) with fluticasone propionate (FP) nasal spray (200 μg/d) in Russian adults suffering from perennial allergic rhinitis (PAR). The duration of treatment was 28 days. The secondary outcomes evaluated safety; patient and physician's satisfaction; quality of life improvement by mini Rhinoconjunctivitis Quality of Life Questionnaire (miniRQLQ). Two hundred and sixty patients were randomized, 257 completed the study and 256 (128 vs. 128) were included in the per-protocol set. Sixty five individual adverse events (AE) were reported in 47 of 260 patients: 19.4% for TAA and 16.8% for FP. Fifty eight AEs were classified as mild, six as moderate and one as severe. The severe case wasn't related to the treatment. All AEs had recovery status at the end of the study with no statistical difference between groups. Patients classified the treatment satisfaction improvement as substantial: 83.6 vs. 87.5%; little: 14.8 vs. 12.5%; no change: 1.6 vs. 0.0% in TAA and FP groups respectively. Physicians qualified the treatment satisfaction as significant: 84.4 vs. 91.4%; little: 14.8 vs. 8.6%; no change: 0.8 vs. 0.0% in TAA and FP groups respectively. No significant differences in patients (p=0.352) and physicians (p=0.082) groups were identified. The change of total score of miniRQLQ from baseline to day 28 was -2.2±1.04 (range -5.2; 0.1) for TAA and -2.2±1.08 (range -5.9;-0.1) for FP with no significant difference between groups (p=0.909). Satisfaction rate and quality of life improvement were similar between TAA and FP. No unexpected AE was identified.

Biography

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