P - SYSTEMIC THERAPY

P884 - Azithromycin SR versus minocycline in the treatment of moderate to severe acne: a phase III, multicentre, randomized, non-inferiority trial

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Introduction: The primary objective of this phase III, multicentre, randomized trial was to evaluate whether azithromycin SR (azithromycin microspheres, powder for oral suspension) was non-inferior to oral minocycline in the treatment of moderate to severe acne. The primary efficacy endpoint was the change from baseline in the GAGS score. Secondary endpoints included changes from baseline in the Leeds score and quality of life (QoL).

Methods: A total of 118 patients were randomized (1:1) to receive azithromycin SR (2 g/week) (n = 58) or minocycline (100 mg q.d.) (n = 60) for eight weeks.

Results: The change from baseline to end of treatment in GAGS score did not differ significantly between the azithromycin SR and minocycline groups [least squares mean -8.69 (95% confidence interval [CI]: -10.33 to -7.05) and -9.16 (95% CI: -10.62 to -7.71), respectively], consistent with the non-inferiority of azithromycin SR to minocycline. The lower limit of 95% confidence interval of the change from baseline to end of treatment in GAGS scores between the 2 groups (95% CI: -2.48 to 1.54) did not exceed the pre-defined non-inferiority margin of -3. In addition, there were no significant differences in improvement of acne graded by the Leeds score and QoL. Twenty-six patients (44.8%) in the azithromycin SR group and 9 patients (15%) in the minocycline group reported gastro-intestinal disorders.

Conclusions: In patients with moderate to severe acne, azithromycin SR is non-inferior to minocycline for primary endpoint (GAGS score), with no significant differences in secondary endpoints.