HAIR DISORDERS

CYCLOSPORINE FOR MODERATE TO SEVERE ALOPECIA AREATA: INTERIM ANALYSIS OF A DOUBLE-BLIND, RANDOMISED, PLACEBO-CONTROLLED CLINICAL TRIAL OF EFFICACY AND SAFETY

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Introduction: Despite widespread use of steroid-sparing agents, particularly cyclosporine, in the treatment of moderate to severe alopecia areata (AA); there are no prospective clinical trials investigating the efficacy of these agents. We present an interim analysis of the first clinical trial evaluating cyclosporine for moderate to severe AA.

Objective: To evaluate the efficacy of cyclosporine compared to placebo at 3 months in patients aged 18 to 65 years with moderate to severe AA.

Materials and Methods: This was a double-blind, randomised, placebo-controlled trial (ACTRN12618001084279). Adults aged 18 to 65 years of age with moderate to severe AA were randomised in a 1:1 ratio to receive 3 months of cyclosporine (4mg/kg/day) or matching placebo. Blinded assessments were conducted monthly and included: physical examination, blood biochemistry, photography and efficacy evaluation using Severity of Alopecia Tool (SALT) score, eyelash and eyebrow assessment scale.

Results: An interim analysis was performed after 2 months. 30 participants (Group 1: n=14; Group 2: n=16) were analysed. At baseline, the mean SALT score was 80% and mean duration of current AA episode was 6 years. While Group 1 had a greater mean change in SALT score (OR 4.67; 95% CI 0.78 to 28.05; p=0.09), greater percentage of participants achieving a 30% improvement (21% versus 6%; p=0.22) and greater percentage of participants achieving 1 grade improvement in eyelash (14% versus 6%; p=0.46) and eyebrow scales (14% versus 0%; p=0.12) compared to Group 2, this did not achieve statistical significance.

Conclusions: Interim analysis after 2 months of treatment do not show a significant

difference between cyclosporine 4mg/kg/day monotherapy and placebo. Any potential benefit associated with cyclosporine treatment is likely to be slower in onset than in other inflammatory skin diseases such as psoriasis and atopic dermatitis. Final evaluation at the primary endpoint of 3 months will also be presented.