Vasoconstrictor potency of fixed combination calcipotriol plus betamethasone dipropionate foam versus other corticosteroid psoriasis treatments

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STUDY OBJECTIVES AND ASSESSMENTS

- The primary objective was to compare the vasoconstriction potential of Ca/BD foam with the other treatments using the human skin blanching test (McKenzie-Stoughton vasoconstriction assay).
- Skin blanching for each treatment was assessed 2 hours after the 16-hour application period by two independent, trained observers.
- Local tolerability was assessed at the same time as skin blanching and at follow-up; safety was assessed throughout the study by evaluation of adverse events (AEs).

STATISTICAL ANALYSIS

- The mean of the two individual skin blanching visual scores were calculated for each treatment, and non-parametric tests were performed.
- Kruskal-Wallis test for the overall effect, and Wilcoxon signed rank test for the pairwise comparisons (Ca/BD foam vs other treatments).

METHODS

PATIENTS

- The study enrolled healthy, non-smoking volunteers aged 18–50 years.
- Subjects were excluded if they received systemic treatments that could interfere with the blanching reaction within 2 weeks, or had used topical CS on the test sites within 4 weeks prior to enrolment.

STUDY DESIGN

- This was a Phase I, single-centre, investigator-blinded, vehicle-controlled, intra-individual comparison study (NCT02973776).
- Each volunteer received a single application, under non-occlusive conditions: Ca/BD foam, clotebasol propionate 0.05% cream (CP, very potent), BD 0.05% ointment (potent), mometasone furoate 0.1% cream (MF, potent), hydrocortisone-17-butyrate 0.1% ointment (HB, moderately potent) and foam vehicle.
- All active treatments resulted in greater skin blanching compared with foam vehicle (Figure 1, Table 2).

RESULTS

- A total of 36 healthy volunteers were randomized and analysed (Table 1).

CONCLUSIONS

- Understanding topical CS potency is important to ensure the appropriate use of treatments for psoriasis.
- This study showed that, consistent with CS potency classifications, the steroid potency of Ca/BD foam was similar to BD ointment and MF cream, significantly stronger than that of HB ointment, but weaker than that of very potent CP cream.
- These findings expand on those from a previously reported Phase I study, which showed that Ca/BD foam was a more potent formulation than Ca/BD ointment.

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REFERENCES