English Title:

LARGE-SCALE EFFICACY AND TOLERANCE OF CALCIPOTRIOL (DAIVONEX®) OINTMENT IN THE TREATMENT OF PSORIASIS

SUMMARY

Justification for the study

The efficacy and good tolerance of calcipotriol (DAIVONEX®) have been demonstrated through comparative, multi centric, and multinational studies.

It was necessary to try to discover if the good benefit/risk ratio revealed in phase III studies was found when calcipotriol ointment is prescribed to a very large number of patients under conditions as close as possible to typical use.

Objectives

To evaluate the efficacy and tolerance of calcipotriol ointment (DAIVONEX®) in a large number of patients with plaque psoriasis.

Patients and methods

This is a multi centric, prospective, non-comparative study including a two-week wash-out phase and a six-week treatment phase.

The evaluation of patients took place every three weeks.

Adult patients of both genders with mild to moderate intensity psoriasis and whose extent of lesions did not exceed 30 to 40 % of body surface area were recruited in 51 dermatology centres in a hospital setting.

The patients who met the eligibility criteria were treated with calcipotriol ointment (50 µg/g) applied twice per day without occlusive dressing.

Results

Five hundred thirty six patients were recruited, and 516 were treated with calcipotriol ointment. Five hundred patients were retained for the efficacy analysis. The average use of the ointment was 34 g per week. The treatment caused the whitening of lesions in 12.4 % of patients.
The reduction in the average PASI between visits 2 and 3 (57.0 %), 2 and 4 (71.0 %), and 2 and "end point") (70.0 %) was always significant (p = 0.0001).

The overall evaluations of the response to treatment done, on the one hand, by patients, and on the other hand, by the investigators, are consistent. At the end of treatment, 73.8 % of patients observed a "whitening" or a "marked improvement." This percentage was 75.7 % based on the opinion of the investigators.

No statistically significant influence was found from gender, age, phototype, and the initial severity of the disease evaluated by the initial PASI on the average percentage reduction in PASI or on the overall evaluation of the response to treatment.

Five hundred fifty patients reported 214 lateral adverse effects. Lesional and peri-lesional irritations were reported for 21.4 % of patients; these are the most commonly observed effects. In the majority of these cases (89.5 % at visit 4), the intensity of these local effects was deemed mild or moderate. They disappeared despite the continuation of treatment.

The number of patients leaving the study due to adverse effects, all types included, was 4.2 %: 21 out of the 505 patients able to be analysed for tolerance.

The results from biological and biochemical examinations did not demonstrate any clinically significant abnormality.

**Conclusion**

The results of this study confirm the efficacy, tolerance, and acceptability of calcipotriol ointment. They also demonstrate that demographic factors such as gender and age, phototype, and the initial severity of the disease do not influence the response to treatment.