

# Calcipotriol: Clinical Trial versus Betamethasone Dipropionate + Salicylic Acid

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The four Italian dermatology centres involved in the clinical trial were: situated at the universities of Milan 2nd (Prof. A. Finzi), Milan 3rd (Prof. C. Crosti), Pisa (Prof. E. Mian) and Trieste (Prof. C. Scarpa).

Ointments were applied *bis in die* for 6 weeks without local occlusion. The two parallel groups of psoriatic patients (en plaque) were randomized within centres (20 + 20 per centre) and were treated as follows:

Group 1: calcipotriol, 50 mg/g.

Group 2: betamethasone dipropionate, 0.05% + salicylic acid, 3% (see Table I).

## RESULTS AND COMMENT

Confidence intervals for the significant differences were obtained by *comparing certain proportions*. As they were rather small, their statistical significance was rather high, but the *p* (probability) obtained in all these comparisons of proportions was 0.7% for the healed group only (better for calcipotriol treatment after 10 weeks; values double underlined in the tables).

The overall impression gained from this trial was that after the first 2 weeks of treatment, the betamethasone +3% salicylic acid treated patients felt better and their clinical appearance was better, whereas in the long term, after conclusion of treatment and the observation interval, the calcipotriol-treated patients experienced a better overall outcome (statistically significant).

Table II. *Calcipotriol versus betamethasone + salicylic acid 3% b.i.d., 6 weeks, no occlusion. - Controlled, multicentre, parallel group, randomized within centres.*

Psoriasis	Calcipotriol	Betamethasone + salicylic acid
No. of cases	80	80
Age, mean	50	50
Sex Male	53	56
Sex Female	27	24

Table I. *Calcipotriol versus betamethasone + salicylic acid*

Centres involved	40 psoriatic patients per centre (20 vs 20)
C. Crosti	Dermatology clinic - Milano
A. Finzi	Dermatology clinic - Milano
E. Mian	Dermatology clinic - Pisa
C. Scarpa	Dermatology dept. - Trieste

Table III. *Percentage of overall investigator's judgement (n = 80 psoriatic patients enrolled).*

	Cal 2°w	Bet 2°w	Cal 4°w	Bet 4°w	Cal 6°w	Bet 6°w	Cal 10°w	Bet 10°w
Excellent	5	0	18	14	39	27	<u>42</u>	<u>19</u>
Good	54	55	47	35	<u>20</u>	<u>35</u>	12	14
Moderate	32	38	<u>14</u>	<u>35</u>	20	20	9	19
Poor	6	7	17	14	16	12	20	18
Null	3	0	4	2	5	6	17	30

Table IV. *Percentage of patient's overall acceptance (n = 80 psoriatic patients enrolled).*

	Cal 2°w	Bet 2°w	Cal 4°w	Bet 4°w	Cal 6°w	Bet 6°w
Excellent	<u>34</u>	<u>19</u>	30	22	<u>35</u>	<u>20</u>
Good	<u>45</u>	<u>64</u>	52	57	49	56
Moderate	12	11	5	9	2	<u>14</u>
Poor	2	4	2	2	2	2
Null	4	0	5	1	1	5