# *PINE-DERIVED LINOLEIC ACID OINTMENT FOR TOPICAL TREATMENT OF STABLE PLAQUE-TYPE PSORIASIS. A COMPARABLE DOUBLE-BLIND STUDY.*

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## SUMMARY

Forty members of the Finnish Psoriasis Association were treated either with pine-oil derived linoleic acid ointment or the vehicle for 4 weeks. By randomization 20 patients were treated with active and 20 patients with placebo ointment. The two groups compared well clinically. A target lesion either on the arm or the leg was followed clinically on a 4-point scale. Scaling, hyperkeratinization, erythema and itching were recorded as: 0 – absent ,1 – mild, 2 – moderate and 3 – severe.
The mean score was calculated at baseline and after 4 weeks. The hyperkeratinization of acanthosis was measured with a Dermascan-C device and the erythema with a photospectrometer.
In the active group mean scaling decreased from 2.3 to 0.3, mean hyperkeratinization from 2.7 to 0.5, mean erythema from 2.9 to 0.5 and mean itching from 1.0 to 0.0. Acanthosis decreased from 0.45mm to 0.25mm and the erythema index from 20.3 to 13.7. In the active group 14 target lesions were totally put into remission and 6 almost completely.
No significant changes in the various parables were observed in the placebo group.

## INTRODUCTION

Psoriasis is a common, genetical skin disease. The majority of the patients suffer from localized, stable plaque-type lesions. This patient group is commonly treated with topical corticosteroids, calcipotriol or phototherapy. Patients with severe, widespread psoriasis are usually treated with oral therapy such as retinoids, methotreate or cyclosporine. In the rare cases hospitalization is necessary. The pathogenisis of psoriasis is still unclear. High amounts of saturated fatty acids such as arachidonic acid in psoriatic epidermis have been proven to be of importance. In a pilot study topical treatment with pine – derived linoleic acid had a beneficial effect on psoriasis of stable plaque-type. The aim of the present study was to evaluate the effect of the same ointment on stable psoriasis plaques in a placebo – controlled manner.

## MATERIAL AND METHODS

The study was carried out as a randomized vehicle (placebo) controlled in 40 patients, all the members of the Finnish Psoriasis Association, with chronic stable psoriasis. The application of the formula was randomized. Meaning that half of the patients received active ointment and the other half of the patients received placebo ointment. The duration of the treatment was 4 weeks and the ointment was applied b.i.d (in the morning and in the evening during study period). One target lesion on the extremities was followed throughout the study period.
Oral informed consent was obtained from all patients prior to the start of treatment.

A clinical evaluation of the target lesion was carried out before the start of treatment and after four weeks using a 4 – point scale: 0 – absent, 1 – mild, 2 – moderate and 3 – severe.
The mean value of the severity of the following parameters were calculated before and after treatment: scaling, hyperkeratinization, erythema and itching. For measuring of acanthosis a Dermascan C (Cortex, Denmark) was used and for measuring of the erythemal index a photospectrometer was used.

**Statistical methods:**

A significance level of 5% was used in the tests and two-tailed tests were applied. Mean was used for estimation of continuous variables.

## RESULTS

Forty Caucasian psoriatic patients were included in the study, 19 females and 21 males (Table 1). All the patients fulfilled the requirements for participation. All the patients completed the study according to protocol. Demographic data for the two treatment groups are presented in Table 1. The two treatment groups are comparable with respect to demographic parameters at baseline. None of the patients had received treatment for their psoriasis within 2 weeks prior to the study. Scaling decreased significantly in both groups, while a decrease in hyperkeratinization, erythema and itching was only observed in the active group. In the active group the target lesion had completely been put into remission in 14 patients and almost completely in the remaining 6 patients. No remission of the lesions were noticed in the placebo group. No adverse effects were observed in either of the 2 treatment groups.

## COMMENTS

The present study confirms the findings in an earlier pilot study (1). Pine-oil derived linoleic acid appears to be highly effective for the treatment of stable plaque – type psoriasis.

**Table 1.**

**Demographic data for the 2 treatment groups.**

| | **Active group** | **Placebo group** |
|---|---|---|
| No. treated | 20 | 20 |
| Sex (female/male) | 9/11 | 10/10 |
| Mean age | 54.1 (SD 3.7) | 53.5 (SD 3.5) |
| Mean duration of psoriasis (years) | 19.7 (SD 3.1) | 20.1 (SD 3.3) |

**Table 2.**

**Changes in target lesions during study.**

| | **Active group** | | **Placebo group** | |
|---|---|---|---|---|
| Localization of target lesion: | | | | |
| Arm | 15 | | 14 | |
| Leg | 5 | | 6 | |
| Parameters at week 0 and week 4: | 0 | 4 | 0 | 4 |
| Scaling | 2.3 | 0.3 | 2.2 | 0.5 |
| Hyperkeratinization | 2.7 | 0.5 | 2.7 | 2.5 |
| Erythema | 2.9 | 0.5 | 2.8 | 2.8 |
| Dermascan measurements: | | | | |
| Acanthosis (mean, mm) | 0.45 | 0.25 | 0.43 | 0.42 |
| Erythemal index | 20.3 | 13.7 | 21.0 | 21.2 |
| Remission rate: | | | | |
| Complete remission | 14 | | 0 | |
| Significant remission | 6 | | 0 | |