NEW COMPLEMENTARY TREATMENT FOR PSORIASIS

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Psoriasis is a chronic, itchy skin disease. Genetic predisposition as well as provoking factors play a role in its severity: the clinical presentation is variable. There are multiple topical and systemic treatment options available. In certain clinical presentations the topical therapy is sufficient.

The study of the topical product family was designed to determine whether its natural oil content (the composition and ratio of the natural oil) would be able to reduce the psoriatic plaques, inflammation and itching.

STUDY TYPE: Open

CONSENT: Prior to the beginning of the study, the participating patients signed an informed consent and an agreement of voluntary participation.

OBJECTIVE: Evaluation of the topical product family in psoriasis to determine its efficacy, adverse effects and tolerability.

CHARACTERISTICS OF THE TESTED PRODUCT

Triphased applications: Successive use of a cleansing gel, ointment, and skin conditioner.

CLEANSING GEL

COMPONENTS: water, oat tar extract, sodium lauryl ether sulfate, ace salicylamid tetrasodium, triethanolamine lauryl sulphate, organic acids, fruit acid complex, cocoyl diethanolamide, carbopol, triethanolamine, methylparaben, potassium EDTA.

APPLICATION: Applied before the use of the ointment.

Scalp: Following wetting of the scalp, a small amount of cleansing gel was applied to the plaques. Washed off after 2-3 minutes using lukewarm water.

Body: Applied to the psoriatic plaques, washed off with lukewarm water after 2-3 minutes. Not to be applied to the face.

OINTMENT

COMPONENTS: wheat germ oil, rice bran oil, evening primrose oil, pet, ast, zinc oxide, jojoba oil, apricot kernel oil, avocado oil, mineral oil, camphor, tea tree oil, burner oil, sandalwood oil, patchouli oil, juniper oil, galbanum oil, orange oil, neroli oil, calendula oil, frankincense oil, coriander oil, clove bud extract, chamomile extract, witch hazel distillate, myrrh oil, essential oils.

APPLICATION: Applied to the psoriatic plaques after washing off the cleansing gel.

Ointment was applied only to severely infiltrated plaques on the scalp.

SEX CONDITIONER

COMPONENTS: olive oil, sesame seed oil, mineral oil, beeswax, sunflower oil, emu oil, lavender oil, eucalyptus oil, rosemary oil, natural menthol, eucalyptus oil, chamomile extract, calendula oil, preservatives.

APPLICATION: Applied to the psoriatic plaques two minutes after using the ointment (without washing it off).

APPLICATION TO THE SCALP WITHOUT OINTMENT: The conditioner was applied to the scalp at night and washed off in the morning using the cleansing gel. The conditioner was reapplied at night without washing the scalp and washed off again using the cleansing gel in the morning. It was recommended to apply the three-component product family twice daily, in the morning and at night.

PATIENT EVALUATION

INCLUSION CRITERIA
- Mild to moderately severe psoriasis without complications
- Both genders, age above 18
- No other current anti-psoriatic therapy
- Signed informed consent

EXCLUSION CRITERIA
- Acute and chronic psoriasis
- Systemic, scabies, psoriasis, ichthyosis, light therapy currently or within the past 3 months
- Topical anti-psoriatic therapy
- Pregnancy, breast feeding
- Known hypersensitivity to any of the components of the products
- Lack of informed consent
- Low compliance

Not applicable to the face, genitalia and flexures.

STUDY PROTOCOL

TIME FRAME

2 weeks of wash-out period. During this phase the patients used only emollients.

Application time of the products: 6 weeks

Total study length: 8 weeks

EVALUATION POINTS

1, 2, 6, 12, 18, 24, 36 weeks

Total number of medical evaluations
- 8

Patients included
- 62

Patients excluded
- 5

Patients evaluated, completed
- 57

APPLICATION FREQUENCY: Twice daily.

EVALUATION OF EFFICACY: The evaluation was based on the Psoriasis Area and Severity Index (PASI) at each of the 8 medical evaluations.

EVALUATION OF IMPROVEMENT

Improved: PASI score higher than baseline

No improvement: PASI decrease < 25%

Moderate improvement: PASI decrease 25-50%

Good improvement: PASI decrease 50-75%

Outstanding improvement: PASI decrease 75-100%

RECORDING OF SIDE EFFECTS

The recording of side effects began on week 3. The characteristics of the side effects, their relation to the product and the additional steps taken were recorded on the datasheet.

EVALUATION OF SIDE EFFECTS

Evaluation of side effects:
- 1, 2, 3, 4, 5, 6 weeks

EVALUATION OF THE RESULT

COMBINED EFFECTS: Tolerability was evaluated at the end of the study based on the statements of the patients.

EFFICACY was evaluated by the physician at the end of the study using the following descriptors: worsened, ineffective, moderate effect, good effect, outstanding effect. The physician’s evaluation was based on the percentage change of the PASI score.
SUMMARY

The study was completed in 57 patients. Five patients dropped out due to lack of compliance and one due to the rejection of informed consent. The patient in the trial had mild to moderately severe psoriasis.

The product proved to be ineffective in five of the 57 patients (9%). 11 patients (19%) had moderate improvement, 25-50% of the skin lesions cleared up. 11 patients (19%) had good improvement, 51-75% of the lesions cleared up. 20 patients (33%) showed outstanding improvement with the regression of 76-99% of the lesions.

27% of the patients developed folliculitis as a side effect that was clearly related to the product family. The folliculitis was noted at a few treated plaques and the surrounding areas on the lower extremities. In all cases, the folliculitis regressed upon discontinuation of the application without further treatment. In one case the folliculitis cleared after topical therapy. No of the patients developed purpura which regressed without discontinuing the application.

No contact sensitization could be noted, which is probably due to the thorough screening applied during patient selection.

Although this product is a cosmetic, due to the previously described circumstances it was recommended that the patients seek the advice of a dermatologist before starting the application in case of noticing side effects they should consult a dermatologist.

The cosmetic effect was evaluated in indifferent by 4% of the patients, as good by 35% of the patients, and as excellent by 16% of the patients.

The evaluation of the treatment by the patients differs from that by the physician. The physician considered the improvement 'outstanding' in 13% of the cases while the patients considered it 'outstanding' in 22% of the cases. The differences can be explained by the fact that the physician's evaluation was based on a pre-determined scale and calculation of the percentage change, while the patient's evaluation was entirely subjective. The patients considered the improvement 'good' where it was only moderate based on the calculated scores. However, many patients would only have given 'outstanding' evaluation for complete clearing of the lesions.

95% of the patients stated that they would continue to use the product, including those who had only moderate improvement. They argued that they were less concerned about side effects since the product was a cosmetic not a medication.

BASED ON THE RESULTS OF THIS STUDY, THE NEW COMPLEMENTARY TREATMENT CAN BE SUCCESSFULLY APPLIED IN MILD TO MODERATELY SEVERE PSORIASIS.