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Evaluation of a Polyherbal formulation (Purodil Gel) in a double blind placebo controlled clinical trial for its efficacy and safety in Acne vulgaris

Introduction

Acne vulgaris is a chronic disease of sebaceous follicles that is multifactorial in etiology and varies in severity as evidenced by lesion type, size, numbers, scarring, and post-inflammatory pigmentary changes. The severity of acne vulgaris (i.e., degree of inflammation and number of lesions) can wax and wane in a given patient. The development of inflammatory lesions often drives acne patients to seek treatment. A variety of drug products, topical and systemic, are currently available to treat acne. Acne occurs more frequently on the face, but can also occur on nonfacial skin (e.g., back, shoulders, chest). Nearly 90% of teenagers have acne, and half of them continue to experience symptoms as adults. Acne has clear detrimental psychosocial effects and may lead to permanent scarring, if untreated.

Aim

The study was conducted to evaluate the efficacy of PURODIL GEL in comparison to placebo in patients with *Acne vulgaris* & its intolerance / side effects on long-term usage.

Material & Methods – A group of 40 patients with mild to moderate acne were enrolled for the study. The clinical trial was initiated to evaluate the efficacy of PURODIL GEL in comparison to placebo in patients with *acne vulgaris*. After assessment by Physician, informed consent was obtained from patients. The purpose of the study, nature of the herbal preparation, the procedures to be carried out and the potential risks and benefits were explained to the study subjects in detail. The final population of each group was 20 persons. During the initial visit, the patients were assigned to two treatment groups. The first group comprised of patients with less than 10 papulo-pustular lesions which were considered as mild. The second group composed of patients with more than 10 papulo–pustular lesions that were considered as moderate Then, patients were assigned to two groups viz. PURODIL GEL and placebo control groups and were recommended to apply twice daily. Also they were advised to come for follow up on 2^{nd} and 4^{th} week of treatment. Inflammation index and the total number of lesions were recorded at every

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follow up. The severity index was determined by Physician according to the lesion counts, the size and the depth of lesions for each patient.

The polyherbal formulation PURODIL GEL and placebo gel were obtained from Aimil Pharmaceuticals (I) Ltd. in coded form and randomly distributed, for evaluating the efficacy of PURODIL GEL in comparison to placebo group in acne vulgaris.

Inclusion Criteria

- ✓ Patients of age groups 14-30 years.
- ✓ Patients with mild to moderate *acne vulgaris*
- ✓ Patients with recurrence of Acne, Dermatitis.

Exclusion Criteria

- ✓ Patients suffering with acute or chronic illness of severe nature.
- ✓ Patients who had systemic complications and menopausal disorders
- ✓ Patients with drug induced acne were excluded from the study.
- ✓ Also some who had systemic or topical treatment during last 3 month were not included.

Statistical Method

After data collection, all the results were analyzed statistically using Student-t test for paired data of different levels of significance. The results were presented as mean± standard error.

Observations:

Total no. of patients studied were 40 (males 20 & females 20). The below given table indicates the age group of patients enrolled for the study.

TABLE 1

Particulars	Age groups (in yrs.)	
	14-20	21-30
Male	16	4
Female	17	3

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After the 3-month study period, decoding of the ongoing therapy was done for PURODIL GEL and placebo.

RESULTS:

The mean age of patients for treatment and control group were 17.20 and 17.90 years respectively, irrespective of sex. The pretreatment records are shown in Table 2.

TABLE 2: Comparison of *acne vulgaris* indices in treatment and control groups before treatment (Mean± SE, n=40)

INDEX	The number of papules	The number of pustules	The number of nodules	Inflammation Index	Severity Index
Control	17.03±2.16	2.13±0.36	1.40±0.28	21.93±1.05	1.55±0.11
Test	19.40±1.05	2.21±0.57	1.68±0.36	23.24±0.12	1.60±0.08
p-value	0.49	0.098	0.589	0.27	1.00

The results indicated that the incidence of papular lesions before treatment in treatment and control group were 19.40 ± 1.05 and 17.03 ± 2.16 respectively and there was no significant difference between them (P= 0.49). Also, there were no significant differences regarding the other disease indices between the two groups (P >0.05) .

The results indicated that the inflammation index and total counts were significantly reduced after 4 weeks of treatment with Purodil Gel. It was showed that the rate of healing of papular and pustular lesions in test and control groups were significantly different ($p<0.001$, and $p<0.05$, respectively). Although, there was no significant difference between the number of nodular lesions in treatment and control groups ($p= 0.240$), the inflammation index in the treatment group was significantly reduced ($p< 0.001$). The results of administration of herbal and placebo cream are tabulated in table 3.

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TABLE 3: Comparison of *acne vulgaris* indices in treatment and control groups after treatment (Mean ± SE, n=40)

INDEX	The number of papules	The number of pustules	The number of nodules	Inflammation Index	Severity Index
Control	16.46 ±2.80	0.60 ± 0.22	0.13 ± 0.08	14.20 ± 2.76	1.6 ± 0.12
Test	2.51 ± 0.90	0.62± 0.25	0.1 ± 0.07	2.03 ± 1.03	1.2 ± 0.07
P value	<0.001	<0.05	0.240	<0.001	<0.001

The results of the present clinical trial indicated that treatment with the Purodil Gel resulted in significant clinical efficacy in comparison with placebo control. Almost 7 fold reduction in papula number was found after 4 weeks of treatment with the Purodil Gel as compared to control group. Also comparing the number of pustules and nodules after 4 weeks, the reduction of inflammation and severity indices in test group were highly significant ($p<0.001$).

Discussion

The analysis of the results revealed significant improvement in the patients receiving PURODIL GEL whereas patients on placebo did not show good results as is evident from the table. Patients on Placebo have now been advised PURODIL GEL for alleviating acne vulgaris and inflammation. All the patients are being followed up further for any recurrence. The treatment was devoid of any adverse effect. Significant relief in acne vulgaris revealed that PURODIL GEL possesses promising anti-acne and anti-inflammatory effects.

Conclusion

The double blind placebo controlled trial suggests that PURODIL GEL is a safe and effective medicine for the treatment of acne vulgaris. The treatment has been found to be devoid of any adverse effects and hypersensitivity reactions.

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