REPORT ON CLINICAL TRIAL OF NEEM GUARD CAPSULE

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REPORT ON THE CLINICAL TRIAL OF "NEEM GUARD" CAPSULE IN SKIN DISEASES

INTRODUCTION :

"Neem Guard" is a poly herbal formulation presented in capsule form by M/s. Goodcare Pharma Pvt. Ltd, Kolkata – 700006. This is a very simple formula with renowned herbs used in various skin diseases and found to be immunomodulator in the recent research. For the purpose of therapeutic evaluation of the said drug in the patients suffering from skin diseases, the present clinical trial was initiated.

AIMS AND OBJECTS :

1. To study the response of the drug "Neem Guard" in skin diseases in general with a motto to study the specific effect of the drug in particular skin diseases, if any.

2. To study the immuno-response of the drug particularly on IgE.

3. To study the safety and toxicity of the drug, if any.

MATERIAL AND METHODS :

Total 57 patients of skin diseases were registered during the course of the trial. The study consists clinical patterns in skin disease and management of the disease with Neem Guard capsule. Out of 57 cases 35 cases had completed the total tenure of the treatment and rest of cases had discontinued at different point of time.

PLACE OF STUDY :

The present clinical study was undertaken at Shyamadas Vaidya Sastra Pith Hospital attached to the Institute of Post Graduate Ayurvedic Education & Research, Kolkata – 700009, during January 2006 to December 2006.

SELECTION OF CASES :

All the patients selected for the present study were interrogated and detailed history was recorded in the case record form. All the patients were thoroughly examined and findings were recorded to establish the final diagnosis. The selection criteria as noted below were followed:-

For the purpose of the present study, patients were registered as per the following criterias:

(i) Age – 20 to 60 years

(ii) Sex – Both sexes
(iii) Subjective features
(a) Classical Clinical Features

(iv) Objective Criterias
(a) Routine Haematological Test
(b) PPBS
(c) Immunoglobulin (IgE)

DRUG SELECTED FOR THE STUDY :

For the purpose of the Clinical Trial in this study, "Neem Guard" capsules a poly herbal compound formulated by M/s. Goodcare Pharma Pvt. Ltd, Kolkata – 700006, approved by the drug control, West Bengal has been selected. The composition of the drug is as follows:

Each capsule contains

Neem patta (Azadirachta indica)	240.40 mg
Neem patta extract (Azadirachta indica)	129.80 mg
Giloy extract (Tinospora cordifolia)	64.90 mg
Amlaki extract (Emblica officinalis)	21.63 mg
Haritaki extract (Terminalia chebula)	21.63 mg
Bahera extract (Terminalia belerica)	21.63 mg

METHOD OF DRUG ADMINISTRATION :

The present study was carried out in two different groups, i.e. trial group and control group, who were randomly divided.

To all the patients of trial group Neem Guard capsule the trial drug was given in the dose of two capsules twice a day, morning and evening with water for a period of sixty days.

To all the patients of control group Placebo capsules containing sugar of milk was given in the similar way as in trial group.

FOLLOW UP :

Follow up study was conducted in all cases at interval of two weeks for 60 days when the subjective features were observed. Immunoglobulin E (IgE) level was estimated before the treatment and after 60 days of treatment.

CLINICAL PATTERN :

The present study includes 57 cases in total who have symptoms of skin diseases. Out of this cases 35 cases had completed the full tenure of the treatment schedule, i.e. 60 days and 22 cases had discontinued the treatment at different times. Patients suffering from skin diseases and registered for the present study were divided into two groups viz. trial group and control group. Trial group consist 38 patients out of which 25 patients had completed the full schedule of treatment and 13 patients had dropped out. Similarly the control group had consisted 19 cases out of which 10 patients had completed the full tenure of treatment and 9 patients had dropped out. The clinical pattern will be discussed in all 57 cases but result will be analysed on observation of findings of 35 patients.

Age Incidence:

Patients of the present study were from 21 to 60 years of age. Patients of different age group as found in this study are given in Table No. 1

Table No. 1: Showing the incidence of different age group

Sl. No.	Age groups (years)	No. of Patients	Percentage
1.	21 – 30	28	49.13
2.	31 – 40	17	29.82
3.	41 – 50	8	14.03
4.	51 – 60	4	7.02
	Total	**57**	**100%**

Sex Incidence:

Patients of both sexes were registered for the present study. The sex groups are given in Table No.2

Table No.2: Showing the Incidence of Sex

Sl. No.	Age groups (years)	No. of Patients	Percentage
1.	Male	31	54.39
2.	Female	26	45.61
	Total	**57**	**100%**

Religion Incidence:

Patients of various religions were included in this study. Patients belonging to different religion are shown in table No. 3.

Table No. 3: Showing the Incidence of Religion

Sl. No.	Religion	No. of Patients	Percentage
1.	Muslim	25	43.85
2.	Hindu	28	49.12
3.	Christian	04	7.03
	Total	**57**	**100%**

Occupational Incidence:

In this study patients belonging to various occupations were included. The occupational history as recorded are shown in Table No. 4

Table No. 4: Showing the Incidence of Occupation

Sl. No.	Occupation	No. of Patients	Percentage
1.	Service	8	14.04
2.	House wives	10	17.54
3.	Labour	18	31.57
4.	Cultivator	10	17.54
5.	Student	2	3.51
6.	Businessmen	6	10.53
7.	Misc.	3	5.27
	Total	**57**	**100%**

Economical Status Incidence:

In this study patients of different income group were recorded and shown in Table No. 5

Table No. 5: Showing the Incidence of Income Status

Sl. No.	Income Status	No. of Patients	Percentage
1.	LIG	40	70.17
2.	MIG	14	24.56
3.	HIG	3	5.27
	Total	**57**	**100%**

Educational Status:

When educational status was enquired, patients of both literate and illiterate groups were found in this series. The educational status as found is given in Table No. 6.

Table No. 6: Showing the Incidence of Educational Status

Sl. No.	Educational Status	No. of Patients	Percentage
1.	Illiterate	7	12.28
2.	Primary	15	26.32
3.	Madhyamik	19	33.33
4.	Higher secondary	9	15.79
5.	Graduate	6	10.53
6.	Post Graduate	1	1.75
	Total	**57**	**100%**

Rural Urban Incidence:

This study included patients from Urban and Rural areas and shown in Table No. 7

Table No. 7: Showing the incidence of Rural and Urban

Sl. No.	Rural / Urban	No. of Patients	Percentage
1.	Rural	17	29.83
2.	Urban	40	70.17
	Total	**57**	**100%**

Incidence of Diet Habit:

Patients included in the present study were found to have both types of diet habits (vegetarian and non-vegetarian), which are presented in Table No. 8.

Table No. 8: Showing the incidence of Diet Habits

Sl. No.	Diet Habits	No. of Patients	Percentage
1.	Non-vegetarian	49	85.96
2.	Vegetarian	8	14.04
	Total	**57**	**100%**

Incidence of Nature of Work:

In this trial nature of work were studied which are presented in Table No. 9.

Table No. 9: Showing the incidence of Nature of Work

Sl. No.	Nature of Work	No. of Patients	Percentage
1.	Sedentary	25	43.86
2.	Moderate	28	49.12
3.	Hardworker	4	7.02
	Total	**57**	**100%**

Incidence of Marital Status:

In this study married and unmarried, both patients are included which are presented in Table No. 10.

Table No. 10: Showing the incidence of Marital Status

Sl. No.	Marital Status	No. of Patients	Percentage
1.	Unmarried	21	36.85
2.	Married	36	63.15
	Total	**57**	**100%**

RESULT AND OBSERVATION:

In this study 57 cases were registered from the out patient department of Post Graduate Ayurveda Education and Research, Kolkata – 700009. The patients were selected following the inclusion, exclusion criterias. The patients suffering from various type of skin diseases were included in this study. In this study the patients were divided in six groups according to the disease. Each of the disease group was further subdivided into two groups randomly, viz. trial group and control group. The number of cases as registered in each disease group are presented in the following table.

Table No. 11: Showing various types of skin diseases registered in that study

Sl. No.	Name of Disease	No. of Patients	
		Group A (Trial Group)	Group B (Control Group
1.	Acne	6	3
2.	Allergic dermatitis	6	3
3.	Contact dermatitis	6	2
4.	Scabies	2	2
5.	Urticaria	10	5
6.	Wet Eczema	8	4
	Total	**38**	**19**

Patients are observed in terms of subjective improvement before treatment during treatment and after treatment.

The response of treatment on subjective criterias as observed in before and after treatment in six different disease groups of patients are presented below:

Response of treatment on Acne:

In this group six patients were registered in trial group out of which 4 patients had completed the treatment schedule and three patients in control group of which two patients had completed the tenure of treatment. The response of treatment in both group of Acne patient as observed are presented the Table No. 12.

Table No. 12: Showing response of treatment on Acne

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Lesion	4	1	75.00	2	2	0.00
Scales	3	1	66.67	2	2	0.00
Black Head	2	1	50.00	1	1	0.00
Scarring	3	0	100.00	1	1	0.00
Pain	1	0	100.00	2	2	0.00

Response of treatment on Allergic Dermatitis:

In this group six patients were registered in trial group out of which four patients had completed the treatment schedule and three patients in control groups of which two patients had completed the tenure of treatment. The response of treatment in both groups of Allergic Dermatitis. Patients as observed are presented the Table No. 13.

Table No. 13: Showing response of treatment on Allergic Dermatitis

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Itching Sensation	4	2	50.00	2	2	0.00
Burning Sensation	3	1	66.67	1	1	0.00
Ulcers	2	1	50.00	1	1	0.00
Black Heads	3	1	66.67	2	2	0.00

Response of treatment on Contact Dermatitis:

In this group six patients were registered. In trial group out of which four patients had completed the treatment schedule and two patients in control group of which one patient had completed the tenure of treatment. The response of treatment in both group of contact dermatitis patients as observed are presented the Table No. 14.

Table No. 14: Showing response of treatment on Contact Dermatitis

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Eruption	4	1	75.00	1	1	0.00
Burning Sensation	3	1	66.67	1	1	0.00
Tingling Sensation	2	0	100.00	1	1	0.00
Lesion	4	2	50.00	1	1	0.00

Response of treatment on Scabies:

In trial group two patients were registered in trial group and they had completed the treatment schedule and 2 patient in control group of which they had not completed. The response of treatment in both group of scabies patients as observed are presented the Table No. 15.

Table No. 15: Showing response of treatment on Scabies

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Pruritus	1	1	00.00	0	0	0.00
Itching Sensation	2	1	50.00	0	0	0.00
Burning Sensation	1	1	00.00	0	0	0.00
Ulcers	1	1	00.00	0	0	0.00

Response of treatment on Urticaria:

In this group 10 patients were registered in trial group out of which six patients had completed the treatment schedule and 5 patients in control group of which two patients completed the tenure of the treatment. The response of treatment in both group of urticaria patients as observed are presented the Table No. 16.

Table No. 16: Showing response of treatment on Urticaria

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Pruritus	6	2	66.67	2	2	0.00
Itching Sensation	4	1	75.00	1	1	0.00
Burning Sensation	5	2	60.00	2	2	0.00
Ulcers	4	2	50.00	1	1	0.00

Response of treatment on Wet Eczema:

In this group eight patients were registered in trial group out of which 5 patients had completed the treatment schedule and 4 patients in control group of which 3 patients had completed the tenure of treatment. The response of treatment in both group of Wet Eczema patients as observed are presented the Table No. 17.

Table No. 17: Showing response of treatment of Wet Eczema

Signs & symptoms	Trial Group			Control Group		
	No. of Patients Before Treatment	No. of Patients After Treatment	% improvement	No. of Patients Before Treatment	No. of Patients After Treatment	% improve-ment
Pain	3	2	33.33	2	2	0.00
Ulcers	5	2	60.00	3	3	0.00
Pruritus	5	2	60.00	2	2	0.00
Secretion	4	1	75.00	3	3	0.00

TOTAL RESPONSE ON SUBJECTIVE FEATURES:

After observation of the response of treatment in different diseased groups, the response of the treatment was also observed on individual symptoms. For this purpose the clinical features of different skin-diseases, were jointly considered and the observations are presented in the Table No. 18.

Table No. 18: Showing the total response of the treatment on subjective features

Sl. No.	Clinical Feature	Trial Group			Control Group		
		No. of Patients Before Treatment	No. of Patients After Treatment	% Relief	No. of Patients Before Treatment	No. of Patients After Treatment	% Relief
1.	Lesion	12	5	58.33	4	4	No improvement
2.	Scales	3	1	66.66	2	2	No improvement
3.	Black Heads	5	2	60.00	4	4	No improvement
4.	Scaring	3	0	100.00	2	2	No improvement
5.	Pain	4	2	50.00	14	14	No improvement
6.	Itching Sensation	6	3	50.00	2	2	No improvement
7.	Burning Sensation	11	4	63.64	3	3	No improvement
8.	Ulcers	8	4	50.00	4	4	No improvement
9.	Eruption	4	1	75.00	1	1	No improvement
10.	Tingling Sensation	2	0	100.00	1	1	No improvement
11.	Secretion	4	1	75.00	3	3	No improvement
12.	Redness	5	2	60.00	2	2	No improvement
13.	Pruritus	12	5	58.33	4	4	No improvement

Apart of the subjective improvements as observed in different diseases groups, the objective criteria, i.e, estimation of IgE level was also estimated before and after treatment. As the number of cases in disease groups were less so a generalized response of the treatment on IgE level was observed and presented statistically in both trial group and control group separately in Table No. 19 and 20 respectively.

Table No. 19: Showing the response of treatment on IgE level in trial group.

IgE	Before Treatment	After Treatment	Decreased Value
Mean	646.12	547.32	98.80
SD ±	291.29	245.82	101.35
SE ±	58.25	49.16	20.26
t			4.87
p	Highly significant <0.001		

Table No. 20: Showing the response of treatment on IgE level in control group

IgE	Before Treatment	After Treatment	Increased Value
Mean	610.00	638.90	-28.10
SD ±	163.65	171.63	18.05
SE ±	51.75	54.27	5.71
t			-4.92
p	Insignificant		

From both of the above tables, it is revealed that positive response was found in trial group whereas negative response was found in control group. The mean IgE level in the trial group before treatment was 642.12 IU/ml was found to reduced to 547.32 IU/ml. The p value was found highly significant. On the other hand the p value in control group was insignificant.

DISCUSSION

In the present clinical study total 57 cases suffering from various types of skin diseases were included. Out of all the patients 22 patients had discontinued the total treatment schedule at different time of treatment and 35 cases (trial group consisted 25 cases and the control group was 10 patients) had completed the course of treatment and could be followed up properly during the treatment schedule of 60 days.

The trial drug **"NEEM GUARD"** capsules were given to all the patients of trial group in the dose of 2 capsules twice daily for a period of 60 days and the control group patients were given the placebo capsule in the same dose for similar duration.

The effect of the treatment on the patients of skin diseases was firstly evaluated on the basis of the specific diseases. The response of the treatment was assessed in terms of subjective improvement in each disease groups. In this study patients were registered from six diseased groups, viz. acne, allergic dermatitis, contact dermatitis, scabies, urticaria, wet eczema.

In acne group of patients positive response was noticed in trial group whereas control group had shown no response. Patients of trial group had shown 100% relief from scarring and pain, 75% relief from lesion, 66.67% from scales and 50% relief from black heads.

In the group of patients suffering from allergic dermatitis had shown more than 50% relief in all the subjective features in the trial group whereas any improvement was not noticed in control group.

The response of treatment in contact dermatitis has shown 100% improvement in tingling, 75% improvement in eruption, 66.67% in burning sensation and 50% improvement in lesion among trial group patients. Among control group of patients any improvement was not noticed.

In scabies group of patients the response of treatment was very minimum. The trial group of patients had shown 50% improvement only in itching sensation, there was no improvement on other subjective features. The control group of patients had shown no response.

In patients suffering from urticaria, had shown good response in trial group and zero response in control group. In trial group 75% improvement from itching sensation, 66.67% from pruritis, 60% from burning sensation and 50% from ulcer was observed.

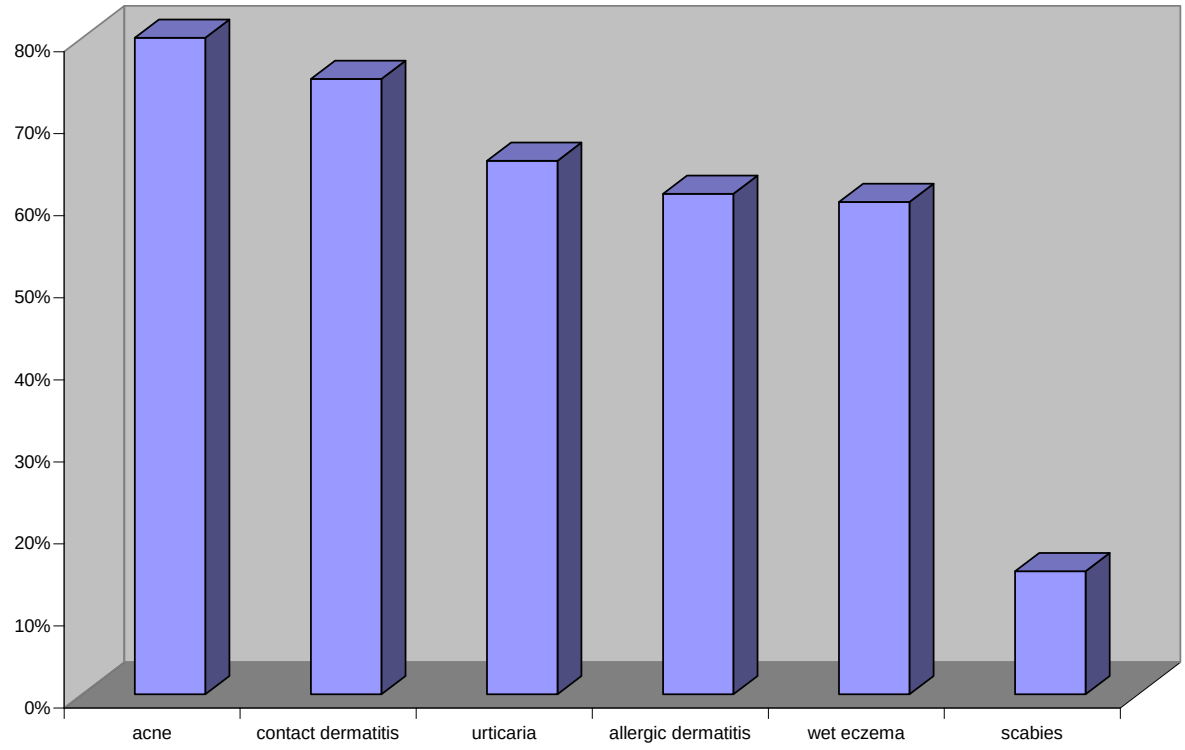
In wet-eczema, good response was observed in trial group and no response in control group of patients. In trial group 75% improvement was noticed in secretion, 60% improvement in ulcer and pruritis and only 33.33% improvement from pain observed.

When the response of treatment in individual disease group was compared on the basis of subjective improvements. It was observed that the response of treatment with **"NEEM GUARD"** capsule in Acne was 78.33%, in contact dermatitis 72.92%, in urticaria 62.92%, in allergic dermatitis 58.34%, in wet eczema 57.08% and in scabies 12.50%.

In this study we have observed the effect of treatment on IgE to assess the immunological response. The effect of treatment on skin diseases on general was taken into consideration and the response on IgE level in trial group was found highly significant ($p < 0.001$) statistically. Similarly the response of treatment on IgE level in control group was observed and found insignificant.

During the clinical study of the **"NEEM GUARD"** capsules in skin diseases any clinical side effect was not noticed.

Fig. 1: Graph Showing Subjective Improvement in Individual Disease Group



CONCLUSION

The product **"NEEM GUARD"** capsule has been found to be effective on lowering IgE level particularly in case of skin diseases as revealed from the study. It has also been found to be an effective product in some selective skin diseases like acne, contact dermatitis, urticaria, allergic dermatitis, wet eczema where the product **"NEEM GUARD"** capsule can safely be prescribed. The effect of the product on scabies was not encouraging. Further longtime study is recommended with specific skin disease.

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