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"CLINICAL EVALUATION OF SAFETY AND EFFICACY OF 'AVALGUJA BEEJA CHURNA'AND 'ARKA TAIL' IN THE MANAGEMENT OF VICHARCHIKA[ATOPIC DERMATITIS]"- A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT-

Due to ignorance towards dietetic, seasonal and daily regimen people are more prone to various kinds of skin disorders. Vicharchika (Atopic dermatitis) is the most common skin disorders. Due to wide spectrum of disease, much prevalence in the society and lack of effective medicament, so disease being chosen for the study. The study was conducted in 50 clinically diagnosed patients of Vicharchika (Atopic dermatitis) and randomly divided into two groups. In group A patients weretreated with Avalguja Beeja Churna(6 gms)) with Ghrita, before meal twice daily for 30 days and Arka Tailtwice daily for 30 days, on the lesion for local application. In group B patients weretreated with Cetrizine tab. (oral 10mg in night) and Clobetasol ointment twice daily for 30 days, on the lesion of Atopic dermatitis. Conclusions: 'Avalguja Beeja Churna' and 'Arka Tail' is safe, cost effective and free from any side effects in the management of Vicharchika [Atopic dermatitis]". It also prevents the relapse considerably.

Key words: - Vicharchika, Atopic dermatitis, Avalguja Beeja Churna, Arka Tail, Cetrizine tab., Clobetasol ointment

INTRODUCTION-

Skin is the largest protective organ of the body. A healthy skin is the mirror image of a good health. The colour of the skin is important biologically, cosmetically and socially. It acts as an effective barrier against the entry of diseases. Skin is the first organ of the body interacting with the environmental agents like physical, chemical & biological agents. Skin ailments affects all ages from the neonates to the elderly & cause harm in a number of ways, such as discomfort, disfigurement, disability etc.

Majority of the skin diseases in *Ayurveda* have been described under the broad heading of 'Kushtha', which are further divided into *Maha Kushtha&Kshudra Kushtha*. Vicharchika one of the *Kshudra Kushtha*¹ runs a chronic course generally considered difficult to cure & even if it is cured relapses are common. Vicharchika has been simulated with the diseases 'Eczema'/ Dermatitis by most of the scholars. Atopic dermatitisis a type of dermatitis, an inflammatory, relapsing, non contagious and itchy skin disorder.²

The global burden of diseases (GBD) Study 2010 estimated the GBD attributable to **15 categories** of skin disease from 1992 to 2010 for 187 countries and eczema fell in to top **50 diseases**. Globally eczema affected approximately 230 million people(3.5% of population as of 2010).

Though many studies have been carried out for this burning problem, still there is need of evaluation of certain drugs clinically on various scientific parameters which could be safe, effective, cheap & readily available in the management of *Vicharchika*, so this clinical trial has been selected.

AIMS AND OBJECTIVES -

- 1. Clinical evaluation of the efficacy of 'AvalgujaBeejaChurna' and 'ArkaTail' in the management of 'Vicharchika'.
- Comparative study of safety and efficacy of 'AvalgujaBeejaChurna&ArkaTail&Tab.Cet rizine and Clobetasol Ointment' in the management of Vicharchika with special reference to Atopic Dermatiti

MATERIAL AND METHODS:

[A] Selection of Cases

A total 50 patients of *Vicharchika* (Atopic Dermatitis) were randomly selected for the present study, from the *Kayachikitsa* OPD and IPD of NIA, Jaipur and Department of Skin and Venereology, SMS Hospital, Jaipur.

[B] Inclusion criteria:

- 1. Patients willing for trial.
- 2. The patients who ages in between 16 70 years were selected.
- 3. The patients having clinical signs and symptoms of *Vicharchika* (Atopic dermatitis).
- 4. The patients having complained less than 5 year duration.

[C] Exclusion criteria:

1. Patients below the age of 16 years and above 70 years.

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- 2. Patients with illness >5 year.
- 3. Patients with long term Steroid and cytotoxic treatment.
- 4. Patients having concomitant illness like HTN, DM-II, and ChronicAtopic dermatitis.
- 5. Patients with evidence of malignancy.
- 6. Smoker/ alcoholics and/or drug abusers.
- 7. Pregnant or lactating women.
- **[D] Study design:** Interventional, Randomized controlled trial, Open label

Ethical clearance: This study was approved by Institutional Ethical Committee (IEC) of National Institute of Ayurveda, Jaipur vide letter No. IEC/ACA/2015/47; dated 21.05.2015, before starting the clinical trial on patients of *Vicharchika* (Atopic dermatitis)

[E] GROUPING AND ADMINISTRATION OF DRUG-

- 50 clinically diagnosed and registered patient of *Vicharchika* were divided randomly into two group .Each group have 25 patients.
- [1] **GROUPA** 25 clinically diagnosed and registered patient of *Vicharchika* were treated by *AvalgujaBeejaChurna* (6 gms)) with *Ghrita*, before meal two times in a day for 30 days and *ArkaTail*twice in a day for 30 days, on the lesion of Atopic dermatitis.
- [2] **GROUPB-** 25 clinically diagnosed and registered patient of *Vicharchika* were treated by **Cetrizine** tab. (oral 10mg in night), **Clobetasol** ointment twice daily for 30 days, on the lesion of Atopic dermatitis.

Trial Drugs-

In the present study, for internal use and forexternalapplication. 'Avalguja Beeja Churna' ³has been selected for oral route and 'Arka Tail' ⁴has been selected for topical application. Keeping all above points in mind the two compound drugs were selected to know their effect in treating *Vicharchika* (Atopic dermatitis).

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1. Avalguja Beeja Churna:

Table- 01: Quantity of ingredients taken for preparation of Avalguja Beeja Churna:

S. no.	Sanskrit Name	Botanical Name	Part Used	Quantity	
1.	Avalguja	Psoralia corylifolia Linn.	Seed	1 Part	

Preparation of Avalguja Beeja Churna:

Churna of the drug was prepared according to the instruction given in "*Churna kalpana*" (*Sharangadhara Samhita*). The drug was prepared in GMP certified N.I.A. Pharmacy, Jaipur. (Batch no. A0097)

2. Arka Tail:

Table- 02: Quantity of ingredients taken for preparation of *Arka Tail*:

S. no.	Sanskrit Name	Botanical Name	Part used	Quantity
1.	Arka	Calotropis procera Linn.	Leaf	16 part
2.	Haridra	Curcuma longa Linn.	Rhizome	1 part
3.	Sarshapa	Brassica campestris Linn.	Seed oil	4 part

Preparation of Arka Tail:

All ingredients of *ArkaTail* were taken as above mention ratio and the *Arkatail* was made as per the *Sharangadhara Tail Pak Kalpana*. The drug were prepared in GMP certified N.I.A. pharmacy, Jaipur. (Batch no. A0097)

Follow-up Study: -

- Follow-up of patient was done on 15th and 30th days of treatment. Improvement in the symptoms if any and other effects were noted down.
- Laboratory investigations were repeated in Group A and Group B after completion of the treatment.

[G] CRITERIA FOR ASSESSMENT

1. Subjective parameters:

For statistical analysis, following signs and symptoms of *Vicharchika*^{5,6} adopted:-

Scoring criteria

1. Kandu (Pruritis)

0 - No itching

- 1 Mild itching not disturbing normal activity
- 2 Occasional itching disturbs normal activity
- ${\bf 3}$ Itching present continuously & even disturbing sleep

2. Daha (Burning)

- 0 No burning sensation
- 1 Mild type of burning not disturbing normal activity
- 2 Occasionally burning disturbing normal activity
- 3 Burning present continuously & even disturbing sleep

3. Strava (Oozing)

- 0 No discharge
- 1 Occasional discharge after itching.
- 2 Occasional oozing without itching.
- 3 Excessive oozing making clothes wet

4. Rukshata (Dryness)

0- No dryness

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- 1- Dryness with rough skin (Ruksha)
- 2- Dryness with scaling (Khara)
- 3- Dryness with cracking (Parusha)

5. Pidikotpatti (Eruption)

- 0 No eruption in the lesion
- 1 Scanty eruptions in few lesions
- 2 Scanty eruptions in at least half of the lesion
- 3 All the lesions full of eruption

6. Vaivarnyata (Discolouration)

- 0 Nearly normal skin colour
- 1 Brownish red discoloration
- 2 Blackish red discoloration

3 - Blackish discoloration

7. Rajii (Thickening of skin)

- 0 No thickening of skin
- 1 Thickening of skin but no criss-cross marking

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- 2 Thickening with criss-cross marking
- 3 Severe lichenification

EASI (Eczema Area and Severity Index) score:

A representative area of eczema is selected for each body region. The intensity of redness(erythema), thickness(induration, papulation, oedema), scratching(excoriation) and lichenification (lined skin) of the eczema is assessed as none (0), mild (1), moderate (2) and severe (3). Half scores are allowed.

Area of involvement

0	1	2	3	4	5	6
No eruption	< 10%	10-29%	30-49%	50-69%	70-89%	90-100%

Erythema	(E)
0	None
1-Mild	Faintly detectable erythema: very light pink
2- Moderate	Dull red clearly distinguishable
3-Severe	Deep/ dark red
Infiltration/ papulation	(I)
0	None
1-Mild	Barely perceptible elevation
2- Moderate	Clearly perceptible elevation but not extensive
3-Severe	Marked and extensive elevation
Excoriation	(Ex)

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0	None
1-Mild	Scant evidence of excoriation with no sign of deeper skin damage (erosion,crust)
2- Moderate	Severe linear marks of skin with showing evidence of deeper skin injury (erosion,crust)
3-Severe	May erosive or crustly lesion
Lichenfication	(L)
0	None
1-Mild	Slight thickening of the skin dissemble only by touch and with skin marking minimally exaggerated
2- Moderate	Define thickening of the skin with skin marking exaggerated so that they form a Criss-cross pattern
3-Severe	Thickened indurated skin with skin marking visibly portraying an exaggerated Criss – cross pattern

Calculation of EASI Score

Head/ Neck	E+I+Ex+LxAreax0.1	(+ + +)x x0.1	
Upper limb	E+I+Ex+LxAreax0.2	(+ + +)x x0.2	
Trunk	E+I+Ex+LxAreax0.3	(+ + +)x x0.3	
Lower limb	E+I+Ex+LxAreax0.4	(+ + +)x x0.4	
EASI	Sum of all above body area		Total score

Maximum Score-70

Minimum Score-0

Hamilton Depression Scale:

(B). Objective parameters:

1] Heamatological Test: Hb%, TLC, DLC, ESR.

2] Biochemical Investigation: RBS

3] Renal Function Test (Blood urea, Sr. Creatinine),

4] Liver Function Test (SGOT, SGPT)

OBSERVATION-

In the present study maximum 34% patients were belonging to 16-30 years of age group, 64 % of the patients were female, 66% patients from Hindu community, 72% were married, maximum number of

patients (42%) were found graduate educational status, maximum patients 66 % were belonged to middle socio-economic status, maximum number of patients (32%) were doing Businessworks, 74 % of patients were not having any particular history of Atopy,maximum patients (50%) were having this disease from 1-3 years, maximum number of patients (64%) had gradual onset, maximum number of patients (30%) were suffered more itching in lesion in winter, maximum number of patients (68%) in this study were having *Sravi*type of *Vicharchika*, maximum number of patients (26%) had lesions on upper extremities, maximum 62% patients were

vegetarian type of diet, maximum number of patients (62%) were having disturbed sleep.maximum 74% patients were having *Vatakaphaja prakriti*, maximum number of patients (58%) were of *madhyamasara*, 64% were of *madhyamasamhanana* and 68% patients were of *madhyama pramana*, maximum number of

patients (62%) from *madhyama satmya*, maximum number of the patients (62%) were having *madhyama satva*, 58% patients were having *madhyama ahara shakti*, 60% were having *madhyama jarana shakti*, 62% patients were having *madhyama vyayama shakti*.

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RESULTS-

TABLE NO. 3: SHOWING EFFECT OF THERAPY ON SUBJECTIVE PARAMETERS (WILCOXON MATCHED PAIRS SINGLE RANKED TEST)

		Mean		Mean	%	SD±	SE±		S
Variable	Gr.	ВТ	AT	Diff.	Relief	SD±	SE±	p value	3
Kandu	Gr. A	2.20	1.76	0.44	20 %	1.044	0.208	> 0.05	NS
Kanau	Gr. B	2.24	1.40	0.84	37.5 %	0.47	0.094	< 0.0001	HS
Daha	Gr. A	0.96	0.76	0.20	20.8 %	0.408	0.081	>0.05	NS
Dana	Gr. B	1.00	0.36	0.64	64 %	0.489	0.097	< 0.0001	HS
Srava	Gr. A	1.56	0.56	1.00	64.1 %	0.957	0.191	< 0.0001	HS
Siava	Gr. B	2.12	1.40	0.72	33.96%	0.458	0.091	< 0.0001	HS
Rukshata	Gr. A	0.84	0.20	0.64	40.3%	0.757	0.151	< 0.0001	HS
Kukshuu	Gr. B	0.60	0.40	0.20	33.33%	0.816	0.163	> 0.05	NS
Pidika	Gr. A	1.20	0.20	1.00	83.33%	0.912	0.182	< 0.0001	HS
1 winu	Gr. B	0.88	0.60	0.28	31.81%	0.458	0.091	< 0.05	S
Vaivaranyat	Gr. A	1.96	1.16	0.80	68.96%	0.50	0.10	< 0.0001	HS
а	Gr. B	1.76	1.08	0.68	38.63%	0.69	0.138	< 0.0001	HS
Rajii	Gr. A	0.96	0.24	0.72	75 %	0.678	0.135	< 0.0001	HS
	Gr. B	1.36	1.04	0.32	23.52%	0.802	0.16	> 0.05	NS
EASI Score	Gr. A	10.15	4.06	6.08	59.9 %	4.339	0.867	< 0.0001	HS

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	Gr. B	10.43	4.74	5.69	54.55%	4.31	0.861	< 0.0001	HS
Hamilton	Gr. A	3.64	0.92	2.72	74.72%	1.173	0.234	< 0.0001	HS
D.S.	Gr. B	2.16	0.48	1.68	77.77%	1.464	0.292	< 0.0001	HS

(HS: Highly Significant

S: Significant

NS: Non Significant)

In Group A, patients were treated with *Avalguja Beeja Churna* in *a* doseof6 gm with *Ghrita* two times in a day before meal and *Arka Tail* for local application twice in a day, shown highly significant results (p value: P < 0.01, P < 0.001, P<0.0001) regarding subjective parameters; EASI Score, *Srava, Rukshta, Pidika, Vaivarnyata, Rajii*, Hamilton depression scale with percentage relief of 59.9%, 64.1%, 40.3%, 83.33%, 68.96%, 75%, 74.72%. In *Kandu* and *Daha* shown no significant result (p value >0.05) with percentage relief of 20%, 20.8%.

In Group B, shown highly significant results (p value : P < 0.01, P < 0.001, P < 0.0001) regarding subjective parameters; *Kandu, Daha, Srava, Vaivarnyata*, EASI Score and Hamilton depression scale with percentage relief of 37.5%, 64%, 33.96%, 38.63%, 54.55%, 77.77%. In *Pidika* shown significant result (p value <0.05) with percentage relief of 31.81% and *Rukashta* and *Rajii* have shownno Significant Result.

TABLE NO. 04: SHOWING EFFECT OF THERAPY ON LABORATORY PARAMETERS (OBJECTIVE PARAMETERS): (PAIRED 'T' TEST)

Variable	Gr.	Mean		Mean	% Relief	SD±	SE±	t	P value	S
		ВТ	AT	Diff.				value		
Hb%	A	12.13	12.30	0.176	1.45%	1.866	0.373	0.471	> 0.05	NS
(Gm %)	В	12.10	12.12	0.02	0.16%	0.404	0.08	0.247	> 0.05	NS
TLC	Α	8456	6708	1748	20.67%	3268	653.7	2.674	< 0.05	S
	В	7691	7736	45.2	0.58%	859.8	171.9	0.262	> 0.05	NS
ESR	A	19.64	13.16	6.48	32.99%	8.98	1.797	3.605	<0.001	HS
	В	16.88	15.32	1.56	9.24 %	3.906	0.7812	1.997	> 0.05	NS
Eosinophil	A	5.92	3.20	2.72	45.94%	2.59	0.518	5.250	<0.0001	HS
	В	3.16	2.44	0.72	22.72%	1.137	0.227	3.166	<0.001	HS
RBS	A	88.84	94.4	5.56	6.25%	25.98	5.19	1.070	> 0.05	NS
	В	98.98	99.88	0.90	0.9 %	2.432	0.486	1.850	> 0.05	NS
SGOT	A	34.88	39.88	5	14.33%	12.51	2.503	1.998	> 0.05	NS

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	В	32.12	33.12	1	3.11 %	3.606	0.7211	1.387	> 0.05	NS
SGPT	A	24.32	24.56	0.24	0.98 %	8.303	1.661	0.144	> 0.05	NS
	В	36.36	37.40	1.04	2.86 %	3.385	0.677	1.536	> 0.05	NS
B.Urea	A	33.16	32.64	0.52	1.56 %	5.157	1.031	0.504	> 0.05	NS
	В	27.84	25.08	2.76	9.91 %	6.869	1.374	2.009	> 0.05	NS
S.Cret.	A	0.72	0.692	0.028	3.88 %	0.277	0.055	0.504	> 0.05	NS
	В	0.96	0.98	0.02	2.08 %	0.236	0.047	0.423	> 0.05	NS

(**Hb-**Haemoglobin; **TLC-**Total Leucocytes Count; **ESR-**Erythrocyte Sedimentation Rate)

In Group A, ESR and Eosinophill shown highly significant result regarding objective parameters with giving (percentageofdecreased) an improvement of 32.99%, 45.94%. TLC shown significant result 20.67% and Hb, Blood Urea, S. Creatinine, SGOT, SGPT have shown no significant result. **In Group B,** all objective parameters have no significant result except Eosinophill (highly significant result)

TABLE NO. 05: INTERGROUP COMPARISON IN SUBJECTIVE PARAMETERS OF GROUP A & B (MANN-WHITNEY TEST)

Variable	Group	(AT-BT) Diff. mean	SD±	SE±	P	S
Kandu	A	0.44	1.044	0.2088	> 0.05	NS
Kanau	В	0.84	0.4726	0.0945		
Daha	A	0.20	0.3742	0.0748	< 0.001	HS
Dana	В	0.64	0.5066	0.1013		
C	A	1	0.9345	0.1869	> 0.05	NS
Srava	В	0.72	0.4583	0.0916		
Rukshata	A	0.64	0.8981	0.1796	< 0.001	HS
Kuksnaia	В	0.20	0.8165	0.1633		
n: 1:1	A	1	0.9129	0.1826	< 0.001	HS
Pidika	В	0.28	0.4583	0.0916		
Vaivaranyata	A	0.80	0.5	0.1	> 0.05	NS

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	В	0.68	0.6904	0.1381		
Rajii	A	0.72	0.6782	0.1356	> 0.05	NS
Кији	В	0.32	0.8021	0.1604		
T. G. G	A	6.08	4.339	0.8679	> 0.05	NS
EASI Score	В	5.69	4.310	0.8619		
Hamilton D.S.	A	2.72	1.173	0.2347	< 0.001	HS
Hammon D.S.	В	1.68	1.464	0.2928		

TABLE NO. 06: INTERGROUP COMPARISON IN LAB INVESTIGATION (OBJECTIVES PARAMETERS) OF BOTH GROUPS: (UNPAIRED'T' TEST)

Variable	Gr.	(AT-BT) Diff. mean	SD±	SE±	t value	P	S
Hb%	A	0.176	1.866	0.3733	0.3875	> 0.05	NS
	В	0.02	0.4041	0.0808			
TLC	A	1748	3273.1	654.62	2.618	< 0.05	S
	В	45.2	857.69	171.54			
ESR	A	6.48	9.068	1.814	2.411	< 0.05	S
	В	1.56	3.906	0.7812			
Eosinophill	A	2.72	2.626	0.5251	3.425	< 0.001	HS
	В	0.72	1.137	0.2274			
RBS	A	5.56	22.74	4.549	0.4416	> 0.05	NS
	В	0.96	2.432	0.4865			
SGOT	A	5	12.407	2.481	1.331	> 0.05	NS
	В	1	3.606	1.653			
SGPT	A	0.24	8.266	0.678	0.5149	> 0.05	NS

	В	1.04	3.391	1.755			
B. Urea	A	0.52	5.072	1.014	1.356	> 0.05	NS
	В	2.76	6.891	1.378			
S. Creat.	A	0.028	0.2769	0.0553	10.165	< 0.0001	HS
	В	0.02	0.2363	0.0472			

DISCUSSION:

PROBABLE MODES OF ACTIONS OF THE DRUG:-

1. AVALGUJA BEEJA CHURNA:-

- Avalguja Beeja Churna containing only Bakuchi. Drug Bakuchi⁷ has Katu, Tikta Rasa and Laghu, Ruksha Guna which act on vitiated Kaphadosha. Vicharchika is Kapha predominant disease so drug Avalguja Beeja Churna works as DoshapratyanikaChikitsa. Bakuchi act as Kushthaghna i.e. VyadhipratyanikaChikitsa.
- Bakuchi hasKaphavatahara property and directly acts on the causative doshas.By virtue of its Rasayana property Bakuchi supposed to increase both qualitative and quantitative improvement of all dhatus of the body.
- Bakuchi has Kushthaghna, Kandughna, Raktashodhaka, Twagdoshahara, Krimighna, Balya and Rasayana properties, which clearly explain its mode of action in Vicharchika.
- Modern research proved that Bakuchi has hepatoprotective activity, anthelmintic effect, anti-inflammatory, pesticidal activity, antitumor activity, antibacterial, antifungal activity, so breaks pathology.⁸

2. ARKA TAIL:-

• Arka Tailcontaining drug Arka, Haridra, Sarshapa tail.

• Arka⁹has Katu-Tikta rasa, Laghu-Ruksha-Tikshna guna, Ushna veerya, it act asBhedana, Deepana, Krimighna, Sophahara, Vatahara, Vranahara, Vishaghna, Kusthaghana, Kandughna.

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- Haridra¹⁰has Katu-Tikta rasa, Laghu-Ruksha guna, Ushna veerya, it act as Kushthaghna, Kandughna, Raktaprasadana, Raktavardhaka, Vishaghna, Anulomana, Shothahara, Varnya, anti-inflammatory activity.¹¹
- Sarshapa tail has Katu-Tikta rasa, Tikshna, Snigdha guna, Ushna veerya, it act as Lekhana, Varnya, Krimighna, Jantughna, Kushthaghna. Oil is a skin and mucous membrain irritant, Emetic stimulant, digestive stimulant, antipruritic, and sporostatic, antifungal.¹²

Upon topical application, the active principle of the *Tail* reaches to the deeper tissues through *Siramukha&Swedavahisrotas* by virtue of its stains it with its *Sukshma* and *Tikshna* property. Due to its *Ushna*, *Laghu*, *Ruksha* properties it removes the obstruction in *Swedavahisrotas* and allows the local toxins to flow out through the *Sweda*, thus clearing out the micro channels. In most of the patients *Kandu* was relieved significantly due to the *Kusthaghna* and *Kandughna* properties of drugs of *Arka Tail*

CONCLUSION:

- ★ Avalguja Beeja Churna and Arka Tail providess very good result in symptoms of Sravi Vicharchika (wet eczema) like, Srava, Pidika, etc.
- ★ The study has revealed that there was no adverse effect on renal and liver functions, with which it can

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be concluded that the drug *Avalguja Beeja Churna* is safe for oral use in the patients of *Vicharchka* (Atopic dermatitis).

- ★ The Ayurvedic medicine Avalguja Beeja Churna is non sedative as Cetrizine has sedative effects; on the other hand Clobetasole on prolonged application causes dry skin which is not evident in the application of Arka Tail.
- ★ The patients of *Vicharchika* without treatment showed the recurrence of symptoms which confirms that *Vicharchika* is a *Chirakari vyadhi* (difficult to treat).
- ★ This Clinical study proves that most of the *Ayurvedic* drugs used in this research project possess blood purifier, anti-inflammatory, antihistaminic, antifungal, antibacterial and immunomodulator properties.¹³
- Thus, finally we can conclude that 'Avalguja Beeja Churna' and 'Arka Tail' are safe, cost effective and free from any side effects in the management of Vicharchika[Atopic dermatitis]". It also prevents the relapse considerably.

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