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Clinical Study To Evaluate The Effect Of Haridra Taila Pratimarsha Nasya And Oral Administration Of Haridra Khanda In The Management Of Pratishyaya In Children

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ABSTRACT

Pratishyaya(Rhinitis) is one of the common respiratory disorders in children known for its re occurrance and chronicity. Reoccurrence can be attributed to low immunity in children. It is commonest *Nasagata roga* (nasal disorder) and a *urdhvajatrugata vikara* (disorders of above clavicle). *Vata* and *Kapha* are the predominant *doshas* involved. Pratishyaya can be corelated to rhinitis, as the clinical features are similar. Rhinitis is a disorder involving upper respiratory tract. Approximately 40% of children experience Rhinitis (common cold). In P*ratishyaya chikitsa*, *vatakaphahara dravyas* are recommended. *Haridra* is a drug which is known for its antiallergic and anti-inflammatory properties, with this aim, in the present study *haridra khanda* and *haridra taila* are selected for trial. **Objective:** To assess the efficacy of *Haridra taila* as *pratimarsha nasya* and oral administration of *Haridra khanda* in the management of *pratishyaya* in children **Intervention:** *Haridra taila* for *Pratimarsha nasya* 2 drops twice a day and *Haridra khanda* 3grams twice a day with milk for 7 days. **Methodology**: Research Design - A single arm open labelled clinical trial on 20 children with *Pratishyaya*. *A*ssessment of subjective parameters was done using a special scoring pattern on day 1 day 4 and day 8 of the treatment. **Results and Conclusion:** There was statistically significant reduction in the clinical features of pratishyaya was noted with the P value 0.005. Hence it was inferred that the intervention selected for the present study is effective in the management of *Pratishyaya* in children between the age group of 3-6 years.

Key words: Children, *Pratishyaya*, Rhinitis, *Haridra khanda, Haridra taila*, P*ratimarsha Nasya*

INTRODUCTION

Pratishyaya is one of the common problems during childhood which disturbs the daily routine and increases the school absences and hence prompt management will help both parents as well as children. The disease, in which *kaphadi dosha* gets dragged by *vayu* and are expelled out through nostrils, is called "*Pratishyaya* [1]. Vitiated *vata*, pitta and *kapha* together with rakta or separately are the dosha involved. Due to various etiological factors aggravation of vayu will occur. Aggravated vayu drags the previously stagnated kapha and other doshas towards nostrils/ external nares and thus precipitates *pratishyaya*. The characteristic features of *pratishyaya are nasasrava*[running nose], *Graauparodha*[nasal obsrtuction or congestion], *shirashoola*[headache], *shirogaurava*[heaviness of head], *jwara*[fever], *kasa*[cough], *kaphotklesha*[phlegm], *swarabheda*[hoarsness of voice], *aruchi*[anorexia], *klama*[tiredness [2]. Depending upon the onset pratishyaya, the management differs. If amavastha of pratishyaya is left untreated or mismanaged leads to severe and more complicated stage i.e *Dushta pratishyaya*[3]. The symptom of rhinitis shows resemblance with the *lakshanas* of *pratishyaya*, hence *Pratishyaya* can be considered as Rhinitis.

Rhinitis affects people of all ages. The incidence of the rhinitis varies by age with highest prevalence in children below 5 years. Around 40% of children suffer from rhinitis. Rhinitis is a condition characterized by inflammation of the nasal passages. It can be caused by various factors, such as allergies, infections, or irritants in the environment. The prevalence of rhinitis in children is increasing worldwide, and it can significantly impact their quality of life. Rhinitis in children can have various causes, including allergic rhinitis, non-allergic rhinitis, and infectious rhinitis [4].

In recent years, there has been growing interest in using Ayurvedic medicine as a holistic approach to manage rhinitis in children. In the management of rhinitis in children, Ayurvedic medicine takes a

comprehensive approach that includes lifestyle modifications, dietary changes, herbal remedies, and other holistic treatments. A study investigated the use of Ayurvedic herbal formulations in children with allergic rhinitis [5]. The study found that the herbal formulations significantly reduced nasal symptoms, such as sneezing and nasal congestion, compared to a placebo group. Another study explored the use of Nasya, a nasal administration of medicated oils, in children with allergic rhinitis [6]. The study found that *Nasya* therapy significantly improved nasal symptoms and quality of life in children with allergic rhinitis. Furthermore, evaluated the effectiveness of Ayurvedic interventions such as *Panchakarma* therapy, which involves detoxification and rejuvenation techniques, in children with chronic rhinitis [7]. The study showed that *Panchakarma* therapy significantly reduced nasal symptoms and improved overall well-being in children with chronic rhinitis.

By addressing the root cause of the condition, Ayurvedic management can provide long-term relief from rhinitis in children. In Ayurveda, rhinitis in children is seen as an imbalance of the doshas, particularly the *Vata* and *Kapha* doshas. This imbalance can be caused by factors such as poor digestion, weakened immunity, and exposure to allergens. Ayurvedic management of rhinitis in children focuses on restoring the balance of these doshas through various interventions. Methods to improve the immunity in the child would prevent reoccurrence and complications. Therefore, as a primary work there are needs for a better management and prevention of the disease *pratishyaya.* Haridra is a drug that is easily available as well as mentioned by acharyas. It is used as an antioxidant and possesses various beneficial properties such as anti-allergic, anti-inflammatory, anti-septic [8]. In the present study main formulation for controlling the allergic condition, which acts on immunity i.e *haridra khanda* has been selected as for oral administration and *haridra taila pratimarsha nasya.* Respiratory system is in continuous contact with the external environment since birth and is considered as prime site of hyper sensitization. Due to continuous changing in life style, urbanization, increased pollution, resistance to antibiotics, are the challenge to treat *pratishyaya*. Negligence of acute stage of disease leads to chronic stage. i.e Dushta pratishyaya. Therefore, in this study an effort has been put forth to do analytical study on pratishyaya by using the drug, *Haridra.*

OBJECTIVES

- To assess the efficacy of *Haridra taila Pratimarsha nasya* and oral administration of Haridra khanda in the management of *Pratishyaya*[Rhinitis] in children (3-6 years)

METHODS AND MATERIALS

Study design: Open labeled single arm prospective clinical trial

Sample size:20

Selection of patients:

The patients fulfilling the inclusion criteria, attending the OPD of Department of *Kaumarabhritya* with the complaint of *pratishyaya* fulfilling the diagnostic criteria were selected.

Diagnostic criteria

On the basis of symptoms of *pratishyaya*-

- *Nasa srava* [Nasal discharge]
- *Kshavathu* [Sneezing]

Associated with or without symptoms like-

- *Nasagrapaka* [Redness of nose]
- *Granavrodha* [Nasal congestion]
- *Kasa* [Cough]
- *Aruchi [*Anorexia]
- *Swarabheda* [Hoarseness of voice]
- *Shirashoola* [Headache]
- *Netrasrava [*Watering of eyes]

INCLUSION CRITERIA:

- Children between the age group of 3-6 years.
- Children with *Pratishyaya* of recent onset within one week.
- Children irrespective of gender, religion and socio-economic status fulfilling the diagnostic criteria.

EXCLUSION CRITERIA:

- Congenital anomalies related to respiratory system.
- Lower respiratory tract infection.
- *Jwara* (>100°F)
- *Dushtapratishyaya, Raktapratishyaya* and *Sannipatajapratishyaya.*
- Chronic rhinitis, Sinusitis, Asthma, Infectious diseases like T.B. and other systemic disorders which interfere during the course of treatment.

Intervention:
Haridra taila for *Pratimarsha nasya* and *Haridra khanda* for oral administration
Dose:
Haridra Taila: *Pratimarsha nasya*-2 drops in each nostril two times a day [at morning and night]
Haridra khanda :3-4years 2grams 2times in a day with warm milk
4-6years 3grams 2 times in a day with warm milk
Anupana: Milk
Duration of the treatment-7 days
Follow up: - Patients were followed for I week after the completion of treatment
Response for intervention were assessed on 1st, 4th & 8th day. follow up assessment were done on 14thday.
Method of preparation of the study drugs:
Table No : 1 Showing Ingredients of Haridra Khanda[9]

Sl No	Major Ingredients	Proportion
1	*Haridra*	8 pala (384gms)
2	*Goghrita*	6 pala (288gms)
3	*Godugdha*	1 adhaka (3 liters)
4	*Sharkara*	50 pala (2.4 kg)
Prakshepaka Dravyas:		
5	*Shunthi, Maricha, Pippali,*	1 pala (48gms) each
6	*Twak, Ela, Patra, Nagakeshara,*	1 pala (48gms) each
7	*Vidanga, Trivrit,*	1 pala (48gms) each
8	*Haritaki, Vibhitaki, Amalaki*	1 pala (48gms) each
9	*Mustha*	1 pala (48gms) each
10	*Loha Bhasma*	1 pala (48gms) each

Method of preparation: Haridra khanda
Haridra was fried in *Go-ghrita* till it attains dark brown colour. On other side *Sharkara* and *Godugdha* Paka was prepared till the achievement of 2 thread consistency. After that fried Haridra was added to the *Sharkara Godugdha Paka* and Paka was done. After achieving *Avaleha Siddhi Lakshanas, Prakshepaka Dravyas* were added and continuous vigorous mixing was done till the achievement of *khanda paka* i.e granular consistency. *Loha bhasma* of 48gm one among the *prakshepaka dravyas* was added at the end. The ready *Haridra khanda* was cooled and stored. Packing and labelling was done in 50 grams airtight containers.
Table No 2 showing ingredients of *Haridra taila*

Sl No	Ingredients	Ratio
1	*Haridra*	560 gms
2	*Tila taila*	250ml
3	Water	8 liters

Method of preparation:
Haridra is pounded in *khalwa yantra* into coarse powder. Then water was added to prepare *Kashaya*. *Kashaya* is reduced till 1/8th part and filtered. Later *Tila taila* was added to it. *Haridra kalka* is prepared and added to it. The mixture was boiled till *sneha siddhi lakshana*. The *haridra taila* was filtered and stored. Packing and labelling was done in 5ml nozzle bottles.

Assessment Criteria

Effect of the treatment was assessed with the help of detailed performa prepared for the purpose by grading the parameters mentioned below.

Subjective parameters-

- *Ksavathu*[sneezing]
- *Nasasrava*[Nasal discharge]
- *Ghranoparodha*[Nasal congestion]
- *Jwara*[fever]
- *Kasa*[cough]
- *Swarabheda*[hoarsness of voice]
- *Ashrusrava*[watering of voice]

Assessment was done on 1st 4th and 8th day. Follow-up assessment on 14th day.

Outcome Measure: The assessment was done by evaluating the changes in the signs and symptoms during and after treatment as following.

Data Analysis: The information gathered on the basis of above observations was subjected to statistical analysis SPSS Version 21. As the criteria selected for analysis were non parametric hence 'Wilcoxon matched pairs test' was applied for statistical improvement analysis.

OBSERVATIONS AND RESULTS

In the present study total 42 children were screened and 24 were registered and included for the trial and among the 20 completed the study and 4 were dropped out. 14 (58.0%) subjects belonged to the age group of 3-4years and 1 0(42%) subjects belonged to the age group of 5-6years and 15 (63.0%) subjects were males and 9(38.0%) subjects were females. 2(8.3%) subjects belonged to upper middle class, 18(75%) subjects belonged to lower middle class, 4(17%) subjects belonged to lower class and 19(79%) subjects were from semi urban, 5(21%) subjects were from rural. In this present study *nasasrava* in 24(100%), *Kshavathu* in 16(67%), *Jwara* in 8(33.3%),*kasa* in 18(75%), *granoparodha* in 19 (79 %), *Granapitika* in 12 (50 %), nasanaaha in 14 (58 %) and *nasagrapaaka* in 12 (50%) children was observed.

20 subjects who have completed the clinical study were considered for *result*. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 23. The nominal and ordinal data were analyzed using non parametric tests like Wilcoxon Signed Rank test, Friedman's test with Wilcoxon Signed Rank test as post hoc with Bonferroni correction. The differences in the mean values were considered significant at $p<0.001$, $p<0.01$, Significant at $p<0.05$ and non-significant at $p>0.05$.

Table No 3 -Showing Results of Friedman's test on *Nasa srava*

PARAMETERS	N	MEAN RANK	X^2	P-value	REMARKS
Nasa srava BT	20	3.95	89.642	.005	S
Nasa srava DT	20	2.95			
Nasa srava AT	20	1.81			
Nasa srava FU	20	1.28			

On applying Friedman test on *Nasa srava*, there was reduction seen in the mean rank (MR) from 3.95 (BT) to 1.28 (FU) with a X^2 value=89.642, p-value = 0.005. This shows that there is statistically significant improvement on the effect on *Nasa srava* (Running nose). As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change

Table No 4 -Showing Results of Wilcoxon's sign rank test on *Nasa srava*

PARAMETERS	NEGATIVE RANKS			POSITIVE RANKS			TIES	TOTAL	Z-VALUE	P-VALUE	REMARKS
	N	MR	SR	N	MR	SR					
Nasa srava BT-DT	19	15.0	435.0	0	.00	.00	1	20	-5.166	.001	S
Nasa srava DT-AT	18	13.5	351.0	0	.00	.00	2	32	-4.604	.001	S
Nasa srava	14	7.50	105.0	0	.00	.00	6	32	-3.742	.001	S

AT-FU											
Nasa srava BT-AT	20	16.5	528.0	0	.00	.00	0	20	-5.013	.001	S

By the end of the treatment (BT-AT), it was found that 16 subjects had reduction in symptoms, which was statistically significant with z value= -5.246, p-value = 0.001.

Table No 5 – Showing Results of Friedman's test on *Kshvathu*

PARAMETERS	N	MEAN RANK	X^2	P Value	REMARKs
Kshvathu BT	16	3.97	88.745	.005	S
Kshvathu DT	16	2.86			
Kshvathu AT	16	1.67			
Kshvathu FU	16	1.50			

On applying Friedman test on *Kshvathu*, there was reduction seen in the mean rank (MR) from 3.97 (BT) to 1.50 (FU) with a X^2 value = 88.745, p-value = 0.005. This shows that there is statistically significant improvement. As Friedman test was significant, Post hoc Wilcoxon test was performed to interpret the time of significant change.

Table No 6 -Showing Results of Wilcoxon's sign rank test on *Kshavathu*

PARAMETERS	NEGATIVE RANKS			POSITIVE RANKS			TIES	TOTAL	Z-VALUE	P-VALUE	REMARKS
	N	MR	SR	N	MR	SR					
Kshavathu BT-DT	14	15.50	465.00	0	.00	.00	2	16	-5.203	.001	S
Kshavathu DT-AT	12	13.00	325.00	0	.00	.00	4	16	-4.838	.001	S
Kshavathu AT-FU	2	2.50	10.00	0	.00	.00	14	16	-2.000	.046	NS
Kshavathu BT-AT	20	16.50	528.00	0	.00	.00	0	16	-5.246	.001	S

By the end of the treatment (BT-AT), it was found that 20 subjects had reduction in symptoms, which was statistically significant with z value= -5.013, p-value = 0.001.

DISCUSSION AND CONCLUSION

Pratishyaya is one of the common problems during childhood which disturbs the daily routine. The *lakshana* of *pratishyaya* are similar to rhinitis like rhinorrhea, itching in throat and eye, nasal obstruction, nasal congestion, headache, sneezing. Haridra [curcuma longa] is a recommended drug in *pratishyaya*, *kasa*, *twak vikara* etc. *Haridra* has *kasaghna*, *raktashodaka*, *rasayana*, *brimhaniya*, *balya*, and *dhatuposhaka* properties [10]. Its Phyto constituents have proved that it acts antiallergic, anti-inflammatory and immunomodulatory, which indirectly increase the immunity. Immunomodulation is necessary in allergic rhinitis so *haridra* khanda is the best of medicine in allergic rhinitis. *Haridra khanda* contains main ingredient as turmeric. All the *prakshepaka Dravya* in *haridra khanda* are *ushna teekshna guna* and are *agni deepaka* and ama *pachaka*[11] which is very much essential in the management of *pratishyaya* In *pratishyaya* main feature is nasal blockage and nasal congestion, for this *nasya* [12] is best option to open nasal obstruction. H*aridra taila* is prepared out of *haridra* and it was used for *pratimarshya nasya*. *Haridra taila* has antimicrobial, antiallergic actions and it has *ushna*, *teekshna guna* helps in pacifying the *vata* kapha doshas. From above observation it is clearly understood that the combined therapy of oral administration of *haridra khanda* and *pratimarsha nasya* with *haridra taila* may help in relieving features of *pratishyaya* in children.

Rhinitis is a common inflammatory condition characterized by nasal congestion, sneezing, itching, and rhinorrhoea. Recent studies have shown that Haridra Curcuma Longa, also known as curcumin, may have beneficial effects in reducing the symptoms of rhinitis. These studies have found that curcumin has anti-inflammatory properties, which can help reduce the inflammation in the nasal passages and alleviate symptoms such as congestion and runny nose. Furthermore, curcumin has been found to have antioxidant activity, which can help alleviate oxidative damage and reduce the severity of symptoms associated with rhinitis. Additionally, curcumin has been shown to modulate molecular targets involved in inflammatory pathways, suggesting that it may have a direct effect on reducing the underlying inflammation associated with rhinitis. Therefore, the use of *Haridra Curcuma Longa* or curcumin as a supplement or treatment option for individuals with rhinitis may provide relief from symptoms and improve overall quality of life. Though the drug have shown good anti-allergic properties against Respiratory symptoms but the study period was short. Proper assessment of this parameter can be done with longer duration of study. Good total improvement was seen in Comparing baseline to 14th day post treatment,

Haridra Khanda is a well-known Ayurvedic preparation which is in practice since years and showing significant improvement in subjects. As *haridra khanda* is sweet in taste and *anupana* is milk, the palatability will also be easy in pediatric age group. *Pratimarshya nasya* is instilling 2-4 drops of medicaments into the nostrils at any time without much restriction. Daily administration of *haridra taila* may makes mucosa healthier and *taila* may act like barrier in preventing the attack of microbes and allergens into nasal mucosa. Thus, both *Haridra khanda* and *Haridra taila* helps in management of *pratishyaya* in children, which is the need of an hour in pediatric practice in this present scenario.

Conclusion: Oral administration of Haridra Khanda along with *haridra taila pratimarshya nasya* in combination is beneficial for *pratishaya* (Rhinitis). The combined effect of both the intervention was statistically significant, hence oral administration of Haridra Khanda and pratimarshya nasya with haridra taila is effective in pratishyaya in children.

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Figure 1: Preparation of Haridra Taila

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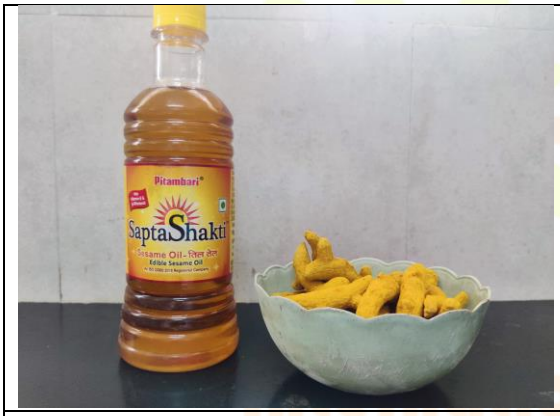
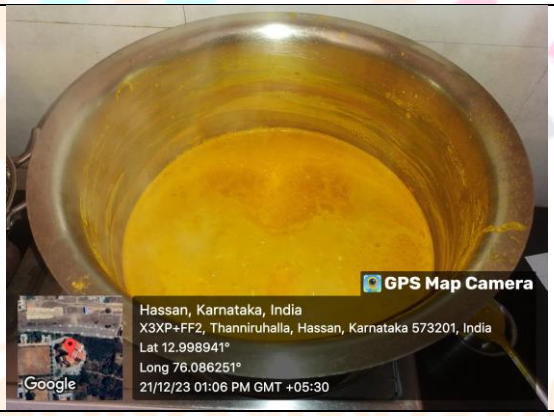
<tr><td> 
</td><td> 
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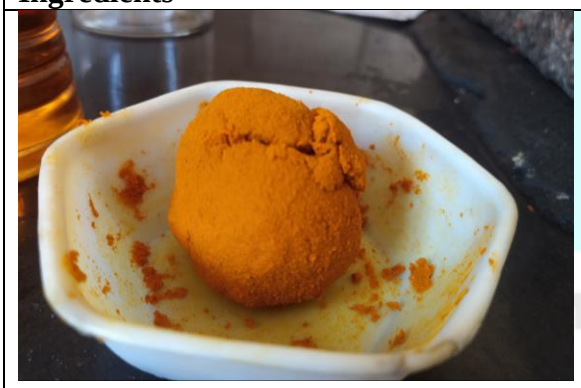
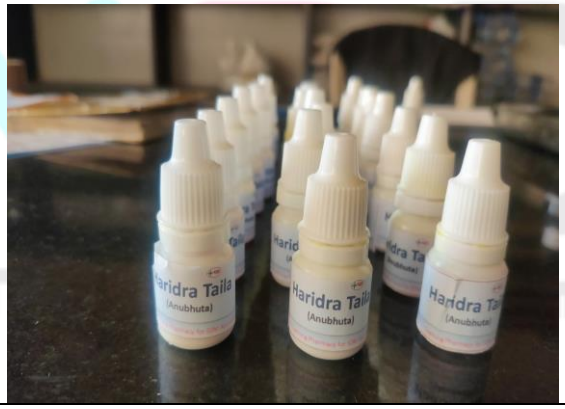
<tr><td>  </td><td> 
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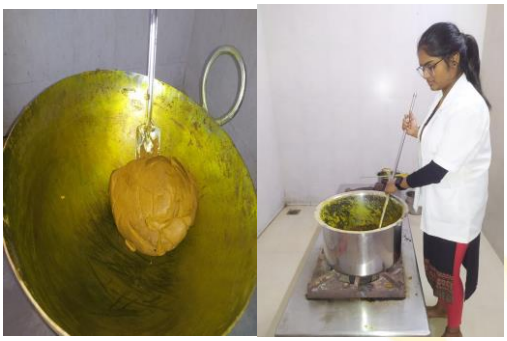
Figure 2 : Preparation of Haridra khanda

INGREDIENTS



Paaka Praparation

Enrollment

Assessed for eligibility n= 42

Excluded n = 18
Not meeting inclusion criteria n = 12
Declined to participate n = 06
Other reasons - 0

Allocation

Allocated to intervention n=24
Received allocated intervention n=24
Not received allocated intervention - 0

Follow-up

Lost to follow-up - 1
Discontinued intervention - 3
(Due to fever)

First Page

Original Research Article – Clinical Study

Title: Clinical Study To Evaluate The Effect Of Haridra Taila Pratimarsha Nasya And Oral Administration Of Haridra Khanda In The Management Of Pratishyaya In Children

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- **Conflict of Interest :** None
- **CTRI REGISTRATION NO:** CTRI/2024/02/062638
- **IEC**

Institutional Ethics Committee

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COMMUNICATION OF DECISION OF INSTITUTIONAL ETHICS COMMITTEE (IEC)

IEC No: SDMHSN/IEC/11-2023

Protocol Title: CLINICAL STUDY TO EVALUATE THE EFFECT OF HARIDRA TAILA PRATIMARSHA NASYA AND ORAL ADMINISTRATION OF HARIDRA KHANDA IN THE MANAGEMENT OF PRATISHYAYA IN CHILDREN

Principal Investigator: Miss BHARATHI BASETTY

Designation and Address: UNDERGRADUATE STUDENT(III BAMS) , SRI DHARMASTHALA MANJUNATHESHWARA COLLEGE OF AYURVEDA & HOSPITAL, BM ROAD, THANNIRUHALLA, HASSAN-573201, KARNATAKA, INDIA

☑ **New Review** ☐ **Revised Review**

☐ **Expedited Review**

Date of Review (D/M/Y): 22.02.2023

Date of previous review, if revised application: Nil

Decision of the IEC:

☑ **Recommended** ☐ **Recommended with suggestions**

☐ **Revision** ☐ **Rejected**

Suggestions/ Reasons/ Remarks: None

Recommended for a period of : ONE Year

Please note *

- Inform IEC immediately in case of any adverse events and serious adverse events.
- Inform IEC in case of any change of study procedure, site and investigator
- This permission is only for period mentioned above.
- Annual report to be submitted to IEC.
- Members of IEC have right to monitor the trial with prior intimation.

23/2/23

Member Secretary
Institutional Ethics Committee
SDM College of Ayurveda & Hospital
Hassan-573201, Karnataka.