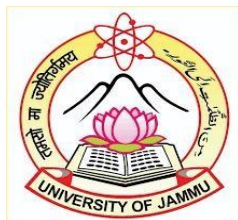


**UNIVERSITY OF JAMMU
JAMMU & KASHMIR**



COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

SYNOPSIS BY

DR. SHUBHAM SHARMA

**FOR THE DEGREE OF AYURVEDA VACHASPATI
M.D. (AYURVEDA) IN KAYACHIKITSA
DEPARTMENT OF PG STUDIES IN KAYACHIKITSA,
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TITLE OF THE SYNOPSIS

**“A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY
TO EVALUATE THE EFFICACY OF *KUSHTHAGHANA MAHAKASHAYA*
AND *KHADIR-TRIPHALADI KASHAYA* IN THE MANAGEMENT OF *EK-
KUSHTHA* WITH SPECIAL REFERENCE TO PLAQUE PSORIASIS”**

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CERTIFICATE OF SUPERVISION

This is to certify that we will supervise the thesis/research work of **DR. SHUBHAM SHARMA** 1st Year M.D. student, the synopsis of which titled as “**A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF KUSHTHAGHANA MAHAKASHAYA AND KHADIR-TRIPHALADI KASHAYA IN THE MANAGEMENT OF EK-KUSHTHA WITH SPECIAL REFERENCE TO PLAQUE PSORIASIS**” is enclosed here with, for the research work to be done during the second and third year of M.D *Kayachiktisa*. The Synopsis submitted is selected and prepared under our guidance.

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TITTLE OF DISSERTATION	“A RANDOMIZED OPEN LABELLED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF <i>KUSHTHAGHANA MAHAKASHAYA</i> AND <i>KHADIR-TRIPHALADI KASHAYA</i> IN THE MANAGEMENT OF <i>EK-KUSHTHA</i> WITH SPECIAL REFERENCE TO PLAQUE PSORIASIS”
ENROLLMENT NO.	

DATED :-

SIGNATURE OF SCHOLAR

INTRODUCTION

Ayurveda is the most ancient healing science and ideal approach for an appropriate life style. *Ayurvedic* texts classify all forms of *Kushtha* as manifestations of "*Tridosha*" indicating that they involve an imbalance of the three *Doshas*.^[1]

Ek-Kushtha is one of the skin disorder explained by *Acharya* in *Kushtha-Chikitsa Adhyaya*. There are two types of *Kushtha* namely *Mahakushtha* and *Kshudrakushtha*. *Ek-Kushtha* is one of *Kshudra-Kushtha*. *Aswedanam*, *Mahavastu* and *Matsyashakalopamam* are the main symptoms of *Ek-Kushtha*.^[2]

अस्वेदनं महावास्तु यन्मत्स्यशकलोपमम् तदेककुष्ठं ||(Ch.Chi.7/21)

Due to resemblance in symptoms "*Ek-Kushtha*" can be co-related with Plaque Psoriasis.^[3] Plaque Psoriasis is a chronic, immune-mediated skin disorder characterized by well-demarcated, raised, erythematous plaques covered with silvery-white scales. It results from hyper-proliferation of keratinocytes due to imbalance in the immune system. Commonly affecting the scalp, elbows, and knees, it is associated with relapsing-remitting course, significant discomfort, and psychosocial impact. Among all types of Psoriasis, Plaque Psoriasis contributes 90% of cases.^[4] In modern era, due to pollution, lack of proper diet, uses of various cosmetic and chemicals all these increasing prevalence of skin diseases day by day.

The Present work is an attempt in this direction – "A Randomized Open-Labelled Comparative Clinical Study To Evaluate The Efficacy Of *Kushthaghana Mahakashaya* and *Khadir-Triphaladi Kashaya* in the Management of *Ek-Kushtha* With Special Reference To Plaque Psoriasis".

खदिराभयामलकहरिद्रारूष्करसप्तपर्णारिग्वधकरवीरविडङ्गजातीप्रवाला इति दशेमानि कुष्ठघ्नानि भवन्ति ||(Ch.Su.4/13)

Acharya Charaka has described fifty *Mahakashyas* also known as *Dashemanis*, in the fourth chapter of the *Sutrasthana* of *Charaka Samhita*. *Kushthaghana Mahakashaya* is one of them which contains a group of ten drugs which are used in *Kushtha Roga*. The drugs of *Kushthaghana Mahakashaya*^[5] are *Khadira*, *Abhaya*, *Amalaki*, *Haridra*, *Aruskara*, *Saptaparna*, *Aragwadha*, *Karaveera*, *Vidanga*, *Jatipravaala*.

खदिरत्रिफलानिम्बपटोलामृतवासकैः । अष्टकोऽयं जयेत्कुष्ठकण्डूविस्फोटकानपि ||(Sah. Yog. Ksh. Pr.1, 2, 4)

Khadira-Triphaladi Kashaya^[6] is described in *Sahasrayogam* contains eight ingredients i.e *Khadira*, *Haritaki*, *Vibhitiki*, *Amalaki*, *Nimba*, *Patola*, *Amirta* and *Vasa* and taken as standard drug due to its proved efficacy in *Ek kushtha*.^[7]

The prevalence rate of psoriasis is 0.44-2.8% worldwide.^[8]

NEED FOR STUDY

Kushtha Roga is a broad term used in *Ayurveda* to refer to various skin ailments. *Ek-Kushtha* is a type of *Kshudra-Kushtha* caused by the *Vata* and *Kapha Dosha*. Its symptoms are quite similar to those of Plaque Psoriasis.^[9]

Psoriasis is a chronic disease that can have substantial psychological and social impact on patient's life. Psoriasis has been shown to affect health-related Quality of Life to an extent similar to the effects of other chronic diseases such as depression, myocardial infarction, hypertension, etc. The modern treatment options not only provide temporary relief but also have serious side effects. Currently the treatment modalities available for the management of psoriasis in contemporary science includes Topical steroid therapy, Corticosteroids, Phototherapy, PUVA therapy, Retinoids and Vitamin D analogue, all of them having their own disadvantages. Thus, the chronic and recurring nature of the disease hampers the Quality of Life to a great extent.^[10] On the contrary, *Ayurveda* has provided immense positive results related to skin diseases. So, it is necessary to have an effective *Ayurvedic* solution for the management of this skin condition known as "*Ek-Kushtha*". Besides of so much work done on this disease, a successful treatment is still not possible in any system of Medicine.

PREVIOUS WORK DONE

In Year 2021

- Dayanand Ayurvedic College and Hospital, Jalandhar ,PUNJAB - A Comparative Study of *Virechana Karma* followed by *Jalauka- Avcharana* and *Virechana Karma* followed by *Khadirashtaka Kwatha* in the management of *Eka-Kushtha* w.s.r. to Psoriasis.
- National Institute of Ayurveda Hospital, Jaipur, Rajasthan - Role of *Saptasama Yoga* and *Kushthaghana Mahakashaya* With *Chakramard Beeja Lepa* In *Dadru*.

In Year 2020

- OPD and IPD , Department of Kayachikitsa,,Maharashtra - Study in the efficacy of *Kushthadi Yoga* in *Ekakushtha* with special reference to Psoriasis A Comparative clinical Study

In Year 2019

- ALL INDIA INSTITUTE OF AYURVEDA, DELHI - To Evaluate the Effect of *Tikta Shatapala Ghrta* with or without *Virechana Karma* in the Management of *Ekakushtha* –Psoriasis (A Randomised comparative clinical study).

In Year 2018

- Jammu Institute Of Ayurveda and Research, Jammu - Clinical evaluation of *Khadir-Triphaladi Kashaya* and *Shweta-Karveeradya Taila* in the management of *Eka-KUSHTHA* w.s.r. to Plaque Psoriasis.
- Institute for Post Graduate Teaching and Research in Ayurved, GUJARAT - Effect of *Rasamanikya* (A Herbomineral formulation) in Psoriasis.

In Year 2016

- Institute for Post Graduate Training and Research in Ayurved, GUJARAT - Impact of *Bhavana* on drug formulation and its effect on *Eka Kushtha* (Psoriasis) in comparison to *Virechana*.

In Year 2014

- Jammu Institute Of Ayurveda and Research,Jammu - Clinical evaluation of *Vamana Karma* and *Nimbadi Churna* with *Patoladi Kwatha* as *Anupana* in the management of *Eka-Kushta* w.s.r. Plaque Psoriasis.

AIM

To compare the efficacy of *Kushthaghana Mahakashaya* and *Khadira-Triphaladi Kashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

OBJECTIVES

1. To study the Etiopathogenesis and Symptoms of *Ek-Kushtha* with special reference to Plaque Psoriasis.
2. To evaluate the efficacy of *Kushthaghana Mahakashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.
3. To re-evaluate the efficacy of *Khadira-Triphaladi Kashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.
4. To compare the effect of *Kushthaghana Mahakashaya* and *Khadira-Triphaladi Kashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

HYPOTHESIS

❖ NULL HYPOTHESIS(H₀)

1. There will be no significant effect of *Kushthaghana Mahakashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.
2. There will be no significant difference between the efficacy of *Kushthaghana Mahakashaya* and *Khadira-Triphaladi Kashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

❖ ALTERNATE HYPOTHESIS (H_A)

H_{A1} : There will be significant effect of *Kushthaghana Mahakashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

H_{A2} : *Kushthaghana Mahakashaya* will be significantly effective than *Khadira-Triphaladi Kashaya Chikitsa* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

H_{A3} : *Khadira-Triphaladi Kashaya* will be significantly effective than *Kushthaghana Mahakashaya* in the management of *Ek-Kushtha* with special reference to Plaque Psoriasis.

REVIEW OF LITERATURE

❖ DISEASE REVIEW

Charaka Samhita

Acharya Charaka has described 18 types of *Kushtha*. Seven types of *Kushtha* have been described as a *Mahakushtha* is detail in *Nidana Sthana*.^[11] In the *Chikitsa Sthana* eighteen types of *Kushtha* have been classified under 7 *Mahakushtha* & 11 *Kshudrakushtha*.^[12]

Sushruta Samhita

Acharya Sushruta first time clearly described the *Amanhsika* (Hereditary) & *Krimi* (Infectious) *Nidana* as a causative factor of *Kushtha*.^[13] *Kushtha* has also been included in list of *Aupasargika Roga*, which may spread from one person to the other.^[14] Acharya Sushruta has also explained the *Dhatugatatva* or *Uttarotar Dhatu Pravesha* of *Kushtha Roga*.^[15]

Ashtanga Hridaya

Acharya Vagbhata has followed Acharya Sushruta regarding classification of *Mahakushtha* & *Kshudrakushtha*.^[16,17]

Bhela Samhita

Bhela Samhita has described *Kushtha Roga* in both *Nidana* & *Chikitsa Sthana*. Specially indicated, polluted water as an etiological factor of *Kushtha*.

Kashyapa Samhita

Kashyapa Samhita has described 18 types of *Kushtha* as Acharya Charaka. except that *Shvitra*, *Vishaja Kushtha* & *Sthulruksha* instead of *Charmkushtha*.

❖ DRUG REVIEW

The trial drug under consideration *Kushthaghana Mahakashaya*^[5] contains *Khadira*^[18], *Abhaya*^[19], *Amalaki*^[20], *Haridra*^[21], *Aruskara*^[22], *Saptaparna*^[23], *Aragwadha*^[24], *Karaveera*^[25], *Vidanga*^[26], *Jatipravalā*^[27].

TABEL NO. 1

Ingredients of *Kushthaghana Mahakashaya*^[5]

[Ref. Cha. Su. 4/13]

S.No.	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1.	<i>Khadira</i> ^[18]	<i>Acacia catechu</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ruksha</i>	<i>Sheeta</i>	<i>Katu</i>
2.	<i>Abhaya</i> ^[19]	<i>Terminalia chebula</i>	<i>Pancharasa (lavanavarjit), Kashayapradhana</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>
3.	<i>Amalaki</i> ^[20]	<i>Emblica officinalis</i>	<i>Panchrasa(lavanarahita), Amlapradhana</i>	<i>Guru, Ruksha, Sheeta</i>	<i>Sheeta</i>	<i>Madhura</i>
4.	<i>Haridra</i> ^[21]	<i>Curcuma longa</i>	<i>Tikta, Katu</i>	<i>Ruksha, Laghu</i>	<i>Ushana</i>	<i>Katu</i>
5.	<i>Aruskara</i> ^[22]	<i>Semecarpus anacardium</i>	<i>Katu, Tikta, Kashaya</i>	<i>Laghu, Snigdha, Tikshna</i>	<i>Ushna</i>	<i>Madhura</i>
6.	<i>Saptaparna</i> ^[23]	<i>Alstonia scholaris</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Katu</i>
7.	<i>Aragwadha</i> ^[24]	<i>Cassia fistula</i>	<i>Madhura</i>	<i>Guru, Mridu, Snigdha</i>	<i>Sheeta</i>	<i>Madhura</i>
8.	<i>Karaveera</i> ^[25]	<i>Nerium indicum</i>	<i>Katu, Tikta</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>
9.	<i>Vidanga</i> ^[26]	<i>Embelia ribes</i>	<i>Katu, Kashaya</i>	<i>Laghu, Ruksha, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>
10.	<i>Jatipravalā</i> ^[27]	<i>Jasminum officinale</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Snigdha, Mridu</i>	<i>Ushna</i>	<i>Katu</i>

Actions of Kushthaghana Mahakashaya^[5]

S.No.	INGREDIENT	DOSHGHANTA	KARMA	PART USED	PROPORTION
1.	<i>Khadira^[18]</i>	<i>Kaphpittashamaka</i>	<i>Kushthaghana</i> <i>Twakrogahara,</i> <i>Kandughana</i> <i>Varnaropana</i>	Bark	1 Part
2.	<i>Abhaya^[19]</i>	<i>Tridoshshamaka</i>	<i>Kushthaghana</i> <i>Shothara,</i> <i>Deepana</i>	Fruit	1 Part
3.	<i>Amalaki^[20]</i>	<i>Tridoshara</i>	<i>Rasayana,Dahapras</i> <i>hmana,</i> <i>Deepana,</i> <i>Rochana</i>	Fruit	1 Part
4.	<i>Haridra^[21]</i>	<i>Tridoshshamaka</i>	<i>Kushthaghana,</i> <i>Shothara,</i> <i>Vranashodhana,</i> <i>Vranaropana</i>	Rhizome	1 Part
5.	<i>Aruskara^[22]</i>	<i>Kapha-Vata</i> <i>Shamaka</i>	<i>Kushthaghana,</i> <i>Deepana</i>	Fruit	1 Part
6.	<i>Saptaparna^[23]</i>	<i>Kapha-Pitta</i> <i>Shamaka</i>	<i>Kushthaghana,</i> <i>Vranashodhana,</i> <i>Vranaropana</i>	Bark	1 Part
7.	<i>Aragwadha^[24]</i>	<i>Vata-Pitta</i> <i>Shamaka, Kapha</i> <i>Shodhak</i>	<i>Kushthaghana,</i> <i>Shothara,</i> <i>Kandugana</i>	Fruit Pulp	1 Part
8.	<i>Karaveera^[25]</i>	<i>Kapha-Vata</i> <i>Shamaka</i>	<i>Kushthaghana,</i> <i>Vranashodhana,</i> <i>Vranaropana,</i> <i>Shothara</i>	Root	1 Part
9.	<i>Vidanga^[26]</i>	<i>Kapha-Vata</i> <i>Shamaka</i>	<i>Kushthaghana,</i> <i>Raktashodhana</i>	Fruit	1 Part
10.	<i>Jatipravalā^[27]</i>	<i>Kapha-Pitta</i> <i>Shamaka</i>	<i>Kushthaghana,</i> <i>Raktaprasadana</i>	Leaf	1 Part

The comparative drug under consideration *Khadira-Triphaladi Kashaya*^[6] contains *Khadira*^[18], *Haritaki*^[19], *Vibhitiki*^[28], *Amalaki*^[20], *Nimba*^[29], *Patola*^[30], *Amirta*^[31] and *Vasa*^[32].

TABEL NO. 2

Ingredients of Khadira-Triphaladi Kashaya^[6]

[Ref. Sah. Yog. Ksh. Pr. 1/1,2,4]

S.No	INGREDIENT	LATIN NAME	RASA	GUNA	VIRYA	VIPAKA
1.	<i>Khadira</i> ^[18]	<i>Acacia catechu</i> <i>Willd</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Ru</i> <i>ksha</i>	<i>Sheeta</i>	<i>Katu</i>
2.	<i>Haritaki</i> ^[19]	<i>Terminalia</i> <i>chebula</i>	<i>Pancharasa</i> <i>(lavanavarjit), Kash</i> <i>ayapradhana</i>	<i>Laghu,</i> <i>Ruksha</i>	<i>Ushna</i>	<i>Madhu</i> <i>ra</i>
3.	<i>Vibhitiki</i> ^[28]	<i>Terminalia</i> <i>bellirica</i>	<i>Kashaya</i>	<i>Laghu,</i> <i>Ruksha</i>	<i>Ushna</i>	<i>Madhu</i> <i>ra</i>
4.	<i>Amalaki</i> ^[20]	<i>Emblica</i> <i>officinalis</i>	<i>Panchrasa(lavanar</i> <i>ahita)</i> <i>Amlapradhana</i>	<i>Guru,</i> <i>Ruksha,</i> <i>Sheeta</i>	<i>Sheeta</i>	<i>Madhu</i> <i>ra</i>
5.	<i>Nimba</i> ^[29]	<i>Azadirachta</i> <i>indica</i>	<i>Tikta, Kashaya</i>	<i>Laghu</i>	<i>Sheeta</i>	<i>Katu</i>
6.	<i>Patola</i> ^[30]	<i>Trichosanthes</i> <i>dioica</i>	<i>Tikta</i>	<i>Laghu,</i> <i>Ruksha</i>	<i>Ushna</i>	<i>Katu</i>
7.	<i>Amirta</i> ^[31]	<i>Tinospora</i> <i>cordifolia</i>	<i>Tikta, Kashaya</i>	<i>Guru,</i> <i>Snigdha</i>	<i>Ushna</i>	<i>Madhu</i> <i>ra</i>
8.	<i>Vasa</i> ^[32]	<i>Adhatoda</i> <i>vasica</i>	<i>Tikta, Kashaya</i>	<i>Ruksha,</i> <i>Laghu</i>	<i>Sheeta</i>	<i>Katu</i>

Actions of Khadira-Triphaladi Kashaya^[6]

S.No	INGREDIENT	DOSHGHANTA	KARMA	PART USED	PROPORTION
1.	<i>Khadira^[18]</i>	<i>Kaphpittashamaka</i>	<i>Kushthaghana</i> <i>Twakrogahara,</i> <i>Kandugana</i> <i>Varnaropana</i>	Bark	1 Part
2.	<i>Haritaki^[19]</i>	<i>Tridoshshamaka</i>	<i>Kushthaghana</i> <i>Shothara,Deepanaa</i>	Fruit	1 Part
3.	<i>Vibhitiki^[28]</i>	<i>Tridoshara (esp. Kaphshamaks)</i>	<i>Charamroga,Krimigana,Shothara</i>	Fruit	1 Part
4.	<i>Amalaki^[20]</i>	<i>Tridosh-hara</i>	<i>Rasayana,Dahaprashmana,Deepana,Rochana</i>	Fruit	1 Part
5.	<i>Nimba^[29]</i>	<i>Kaphpittashamaka</i>	<i>Kushthaghana,</i> <i>Dahaprashamana,</i> <i>Vranashodhana,</i> <i>Kushthaghana</i>	Leaves	1 Part
6.	<i>Patola^[30]</i>	<i>Tridoshshamaka</i>	<i>Kushthaghana,</i> <i>Vranashodhana,</i> <i>Vranaropana</i>	Leaves	1 Part
7.	<i>Amirta^[31]</i>	<i>Tridoshshamaka</i>	<i>Kushthaghana,</i> <i>Raktashodhana</i>	Stem	1 Part
8.	<i>Vasa^[32]</i>	<i>Kaphpittashamaka</i>	<i>Kushthaghana,</i> <i>Shothara,</i> <i>Charmarogahara</i>	Leaves	1 Part

MATERIAL AND METHODS

1. Conceptual Study

Literary aspect of study will be collected from Classical Ayurvedic and contemporary text including the journals and website about the disease and drugs.

2. Clinical Study

- The patients of either sex, suffering from “*Ek-Kushtha*” will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.

PLAN OF STUDY

- **Clinical Study** : For Clinical study, patient will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.
- **Type of Study** : A randomized, open labelled, comparative, pre and post test clinical study.
- **Level of Study** : O.P.D. & I.P.D. level.
- **Period of Study** : 18 months.

FOLLOW UP

- **Follow up** :- on 15th day, 30th day and 45th day
- **Drug free Follow up** :- on 45th day

SAMPLE SIZE

30 patients divided in 2 groups of 15 patients in each group.

❖ Grouping :

GROUP	DRUG	NO. OF PATIENTS
GROUP A (Trial Group)	<i>Kushthaghana Mahakashaya</i> ^[5]	15 patients
GROUP B (Comparative Group)	<i>Khadira-Triphaladi Kashaya</i> ^[6]	15 patients

INCLUSION AND EXCLUSION CRITERIA

❖ INCLUSION CRITERIA

- Patients presenting with classical features of “*Ek-Kushtha*” as per *Ayurvedic* Text and modern literature.
- Patients age between 16 to 60 years irrespective of gender.
- Patients with history of “*Ek-Kushtha*” less than two years.

❖ EXCLUSION CRITERIA

- Age below 16 years and above 60 years.
- Skin disorders other than “*Ek-Kushtha*” shall be excluded.
- Patients with systemic disorders like cardiac illness, bronchial asthma, endocrine disorders which may interfere with the treatment will be excluded.
- Pregnant and lactating woman.
- Chronicity of disease more than two years.
- Patients who have undergone recent surgeries.
- Patients on oral cortico-steroid therapy.

DRUG SELECTION AND PREPARATION

✓ **Collection of drugs :-**

- Ingredients of trial drug *Kushthaghana Mahakashaya*^[5] and *Khadira-Triphaladi Kashaya* will be procured from the authentic sources, identified and approved by Department of *Dravya Guna*, Jammu Institute of Ayurveda and Research, Jammu .

✓ **Preparation :-**

➤ **Trial Drugs :-**

(1) *Kushthaghana Mahakashaya*^[5]

- The raw ingredients of the *Kushthaghana Mahakashaya* will be taken in equal parts.
- *Khadira, Abhaya, Amalaki, Haridra, Aruskara, Saptaparna, Aragwadha, Karaveera, Vidanga, Jatipravala* will be made into coarse powder in the pharmacy of Department of *Rasa Shastra* and *Bhaishajya Kalpana*, Jammu Institute of Ayurveda and Research, Jammu.

(2) *Khadira-Triphaladi Kashaya*^[6]

- The raw ingredients of a *Khadira-Triphaladi Kashaya* will be taken in equal parts.
- *Khadira, Haritaki, Vibhitiki, Amalaki, Nimba, Patola, Amirta and Vasa* will be made into coarse powder in the Pharmacy of Department of *Rasa Shastra* and *Bhaishajya Kalpana*, Jammu Institute of Ayurveda and Research, Jammu.

METHODS OF DATA COLLECTION

❖ **Randomization:-** Randomization will be done by using randomization software from www.randomizer.org .

❖ **Sampling Technique:-**

- Subjects will be randomized in two groups.
- A special Case Report Format (CRF) containing all the necessary details pertaining to the study will be prepared.
- Data obtained in the group will be recorded, tabulated and statistically analysed.

INTERVENTION

➤ **Group A (Trial Group)**

- **Yoga :-** *Kushthaghana Mahakashaya*^[5]
- **Dosage :-** 48 ml twice a day before meals^[33]
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

➤ **Group B (Comparative Group)**

- **Yoga :-** *Khadira-Triphaladi Kashaya*^[6]
- **Dosage :-** 48 ml twice a day before meals^[33]
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

ASSESSMENT CRITERIA

For evaluating the efficacy of drugs, following parameters will be adopted before and after the completion of clinical trial.

❖ **SUBJECTIVE CRITERIA**

1. *Matsyashakalopamam*
2. *Kandu*
3. *Rukshatva*

❖ **OBJECTIVE CRITERIA**

1. Auspitz's Sign
2. Candle grease Sign

GRADING OF THE ASSESSMENT CRITERIA ^[34]

The scoring pattern was adopted on the basis of scoring of NATIONAL PSORIASIS FOUNDATION [NPF] for sign and symptoms of Psoriasis and special scoring pattern was adopted for certain sign and symptoms of *Ek-Kushtha*.

1. Matsyashakalopamam:-^[34]

GRADE	SCORE
No Scaling	0
Mild scaling by rubbing or itching from some lesions	1
Moderate scaling by rubbing or itching from some lesions	2
Severe scaling by rubbing or itching from some lesions	3
Without itching severe scaling from all lesions	4

2. Kandu:- ^[34]

GRADE	SCORE
No itching	0
Mild / occasional itching	1
Moderate (tolerable) infrequent	2
Severe itching frequently	3

3. **Rukshatva**:- ^[34]

GRADE	SCORE
No line on scrubbing by nail	0
Faint line on scrubbing by nail	1
Lining and even words can be written on scrubbing by nail	2
Excessive Rukshata leading to Kandu	3
Rukshata leading to crack formation	4

4. **Auspitz Sign**:- ^[34]

GRADE	SCORE
Absent	0
Present	1

5. **Candle grease Sign**:- ^[34]

GRADE	SCORE
Absent	0
Present	1

INVESTIGATIONS

❖ **Laboratory Investigations [To rule out other ailments]**

- Hb gm%_s
- ESR
- Blood Sugar

CRITERIA FOR OVERALL EFFECT OF THERAPY

The result will be categorized as :-

Complete Remission	100% relief in subjective and objective parameters
Marked Improvement	More than 76% Relief in subjective and objective parameters
Moderate Improvement	51%-75% Relief in subjective and objective parameter
Mild Improvement	26%-50% Relief in subjective and objective parameters
Unchanged	Result below 25% will be considered as unchanged

CONCLUSION

Conclusion will be made on the basis of the observation which is done on subjective and objective parameters. Result will be analyzed statistically and discussed accordingly.

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