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A Comparative Effectiveness of *Kokilakshadi Kashayam* & *Kaishore Guggulu* in the Management of *Vatarakta* W.S.R. Gout – Study Protocol For A Randomized Controlled Trial

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Abstract: Background: Vatarakta can be managed in a number of ways, including with the use of herbs and formulations, as indicated by Ayurvedic texts. However, no systematic data are available on the comparative efficacy of Kokilakshadi Kashayam and Kaishore Guggulu. The purpose of this study is to compare the efficacy of Kaishore Guggulu and Kokilakshadi kashayam in the treatment of Vatarakta patients.
Method and design: In a prospective, single-centered, randomized controlled trial, 60 patients, between 19 and 60 years, diagnosed with Vatarakta, presenting with cardinal features of Vatarakta as per Ayurvedic texts, and the Patients having serum uric acid levels of more than 6mg/dl in females & more than 7mg/dl in males will be split into two groups at random. Patients will receive Kaishore Guggulu in one group and Kokilakshadi kashayam in the other. Guidelines regarding Pathya-apathya will be given. 30 days of treatment will be given to each group. Outcomes will be evaluated on the 15th & 30th (During treatment) & 60th day (post-treatment). The primary outcome will be assessed by looking up the Vatarakta cardinal symptoms' grading. Secondary outcomes will check for improvement in laboratory investigations like changes in Serum uric acid levels and the patient's quality of life.
Conclusion: This trial is the first to compare the efficacy of Kaishore Guggulu and Kokilakshadi Kashayam in Vatarakta patients. Kokilakshadi kashayam is anticipated to alleviate Vatarakta symptoms, demonstrating its efficacy in the treatment of Vatarakta patients.
Trial registration: CTRI/2023/07/055000.
Keywords: Vatarakta, Kokilakshadi kashayam, Kaishore guggul, controlled trial.

I. INTRODUCTION

In today's era due to a sedentary lifestyle, unhealthy food consumption and not doing much physical workout, many metabolic disorders are emerging like- Hyperuricemia, hypertension, diabetes, and dyslipidemia. VataRakta is a metabolic illness as well.*Nidana* of *VataRakta* is *katu amla, ushna, vidahi ahara* and various *vihara*.[1] These *Nidan sevan* vitiated *Vatadosha* and *RaktaDhatu*. Due to the suksham and Drava guna of Vata and Rakta, respectively, this vitiated Vata and deranged Rakta circulate throughout the body very quickly. This results in doshadushyasammurchana in sandhi sthana, particularly pada and angula sandhi, and leads to the sandhi shoola, *sandhi Graha, sandhi shotha, vaivarnya, sparsha asahatva, daha.*[2] The pain in *VataRakta* is described as "*Akhuvisha*" as it gradually spreads and manifests its symptoms.[3]*VataRakta* has been explained decoratively in Brihtrayi i.e. by *Acharya Charaka, Acharya Sushruta*, and *Acharya Vagbhata*. The synonyms of *VataRakta* are *Khudaroga, Vatabalasa* & *AdhyaVata*.[4]

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Gout is a metabolic disease that most often affects middle-aged to elderly men and postmenopausal women. It results from an increased body pool of urate with Hyperuricemia. It is typically characterized by episodic acute arthritis or chronic arthritis caused by the deposition of MSU (Monosodium urate) crystals in joints.[5] The biochemical precursor of Gout is Hyperuricemia. Hyperuricemia is a condition where the uric acid level exceeds the normal range(>7mg/dl in males and >6.0mg/dl in females). Hyperuricemia is due to an excessive amount of synthesis of uric acid or decreased excretion, that causes the crystallization of Monosodium urate crystals in joints, tendons, and surrounding tissue.[6] On keen observation of etiology and symptoms described in modern medicine and Ayurvedic texts, *VataRakta* can be compared with Gout caused by hyperuricemia. Gout has an overall prevalence of 2-26 per 1000 people and a population-wide incidence ranging from 0.2 to 3.5 per 1000 people.Gout is found to have increased prevalence in recent years. In children and premenopausal women, it is uncommon.The peak age of onset in males is between 40 and 50 years.[6]

II. MATERIAL AND METHODS

Literary data will be compiled from different ayurvedic texts *like Charak Samhita, Sushrura Samh*ita etc and relevant modern books , journal etc. Clinical data will be collected from Patients of Gout presented in Institute for Ayurved studies and research Hospital, SKAU, Kurukshetra

1) *Inclusive Criteria:* Diagnosed and confirmed the case of *VataRakta* (Gout); the Patients who have serum uric acid levels of more than 6mg/dl in females & more than 7mg/dl in males with or without any associated features like joint pain and inflammation; will be Randomly selected irrespective of their caste, religion, and sex etc. Patients with an age limit of 19-60 years. Patients of *VataRakta* willing to take ayurvedic medicine and sign the consent form.
2) *Exclusion Criteria:* Patients below aged 19 years and above 60 years; suffering from other forms of Arthritis like Rheumatoid arthritis, Osteoarthritis, Ankylosing spondylitis, Infective arthritis, etc.; Pregnant and lactating mothers; patients showing uric acid level above 9mg/dl; Patients with evidence of malignancy & on chemotherapy drugs; Patients having any disorders like Diabetes mellitus, Cardiac disease, CRF, ARF, etc. and the patients who had a history of Hypersensitivity to the trial drugs and any of its ingredients.
3) *Ethical Consideration:* The Institutional Ethics Committee has given the study approval with no (No. SKAU/ Acad/2022/6740) on dated 2nd November 2022 and is carried out in compliance with standard clinical study protocols (Declaration of Helsinki). The trial registration number is CTRI/2023/07/055000. Informed consent is obtained for all patients. The trial is in the recruitment phase. Procurement of the drug has been done from a reliable pharmaceutical providing quality control report of the drug.

III. RANDOMIZATION

Patients are randomized in a 1:1 ratio to either Group A or Group B.Through a computer – generated randomization sequence. A patient will only be registered once and randomized once.

IV. STUDY DESIGN

In this prospective, randomized controlled trial, Before being randomly assigned, each patient in the research is given an Ayurvedic diagnosis.After randomization, patients in Group A, each Patient will be advised to take Kokilakshadi Kashayam in the dose of 48 ml with 3 gm. Pippali churna as prakshepa Dravya with Normal water twice daily for 30 days. Patients in Group B will be advised to take a Kaishore Guggulu 1500 mg with normal water twice daily for 30 days.

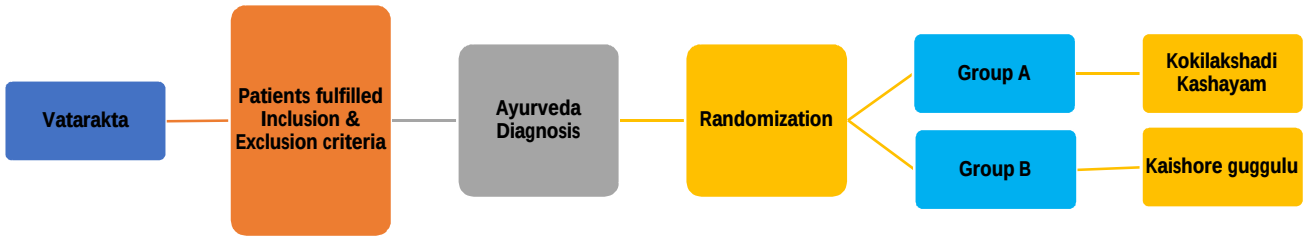


Figure 1: Trial Design

V. OUTCOMES

The primary result will be assessed by comparing the Vatarakta cardinal symptoms listed in Ayurvedic texts. Secondary outcomes will check for improvement in lab investigations and patient's quality of life. Outcomes will be evaluated on 15& 30th (During treatment) & 60th day (post-treatment).

Table no. 1: Assessment Criteria

SR N0.	Symptoms & grading	
1	• *Sandhi Shotha* (Swelling over joints)	
	No swelling	0
	Mild swelling (seen with very careful observation)	1
	Moderate swelling	2
	Bulky swelling	3
2	• *Vidaha* (Burning sensation)	
	Absent	0
	Transient, no approach for its aversion	1
	Frequent, self-approach for its aversion	2
	Regular, seeking medical advice	3
3	• *Raga* (Redness in joints)	
	No Redness	0
	Mild Redness	1
	Moderate Redness	2
	Severe Redness	3
4	• *Toda* (Pricking sensation)	
	No pricking sensation	0
	Mild pricking sensation	1
	Moderate pricking sensation	2
	Severe pricking sensation	3
5	• *Twakvaivarnya* (Discoloration)	
	No discoloration	0
	Mild discoloration of the skin	1
	Moderate discoloration of the skin	2
	Severe discoloration of the skin	3
6	• *Sparsha Asahyata* (Tenderness in joints)	
	No Tenderness	0
	The patient says it is Tendered	1
	Patients say it is Tender with winces	2
	Patients do not allow to touch the affected part	3
7	• *Visphota* (Desquamation status)	
	No Desquamation	0
	Mild Desquamation	1
	Moderate Desquamation	2
	Severe Desquamation	3
8	• *Sandhi Akunchana Prasarana Vedna (pain in joints movements)*	
	No pain	0
	Pain without wincing of face	1
	Pain with wincing of the face	2
	Does not allow passive movements	3

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A. Interventions

Group A - It will be recommended to each patient to take Kokilakshadi Kashayam in the dose of 48 ml with 3 gm. Pippali churna as prakshepa Dravya with Normal water twice daily for 30 days. The drug is a combination of contents as mentioned in Table no 2
Group B - It will be recommended to each patient to take a Kaishore Guggulu. 1500 mg with normal water twice daily for 30 days. The drug is a combination of contents as mentioned in Table no3.

Table no 2: Contents of Kokilakshadi Kashayam

Drug Name	Latin Name	Quantity	Part used
Talmakhana	Asteracantha Longifolia	1 part	Seeds
Guduchi	Tinospora cordifolia	1 part	Stem
Prakashepa-Pippali-Churna (Pipper Loungum)			Fruit

Table no 3: Contents of Kaishore Guggulu

Sr. No.	Ingredient Name	Scientific name (Family)	Part used	Ratio
1.	*Guggulu*	Commiphora Mukul Hook. (Burseraceae)	Resin	768gm
2.	*Haritaki*	Terminalia chebula Retz. (Combretaceae)	Fruits	256gm
3.	*Bibhitaki*	Terminalia bellerica (Combretaceae)	Fruits	256gm
4.	*Amalaki*	Emblica officinalis Gaertn. (Euphorbiacea)	Fruits	256gm
5.	*Amarta*	Tinospora cordifolia (Menispermaceae)	Stem	1.536kg
6.	*Sunthi*	Zingiber officinale (Rosc.) (Zingiberaceae)	Rhizomes	24gm
7.	*Marica*	Piper nigrum Linn. (Piperaceae)	Seeds	24gm
8.	*Pippali*	Piper longum Linn. (Piperaceae)	Fruits,	24gm
9.	*Vidanga*	EmbeliaRibes Burm (Myrsinaceae)	Fruits	24gm
10.	*Tirivrt*	Operculina turpethum (Convulvulaceae)	Root	12gm
11.	*Danti*	Baliospermum montanum (Willd.) Muell- (Euphorbiaceae)	Leaves, root, stem	12gm
12	*Ghrita*			384gm

B. Both Groups

Pathya-Apathya, or specific food (Ahara) and lifestyle changes (Vihara), would be recommended in both groups. These measures are essential for managing Vatarakta in each patient.

C. Statistics

The subjective parameters will be analyzed. The 30 patents in each group will be studied. Unpaired t-test will be applied on the collected data to achieve p value of 0.05. Detailed statistical plan will be developed before data analysis using SPSS and MS Excel.

VI. RESULT

The outcome will be determined based on changes in subjective and objective criterias after applying proper statistics, as per need on the data.

VII. DISCUSSION

With the march of time, the majority of eating habits (*Viruddhahara*), social structure, lifestyle, and environment have been changing. One of the consequences of these changes is also the occurrence of VataRakta. In modern science, NSAIDs (Non-Steroid Antiinflammatory Drugs), Xanthine Oxidase Inhibitors (Allopurinol, Febuxostat), Colchicines, Probenecids & corticosteroids are the most widely used medicine for the treatment of Gout, but these have many side effects when used for a longer duration. Keeping in view of the above limitations and side effects, this study has been chosen to fill the gap of providing a safe and effective line of treatment as Ayurveda provides multiple formulations for *Vatarakta*. So, an effort is made to see whether *Kokilakshadi Kashayam* or *Kaishore Guggulu* is effective in the management of *Vatarakta.*

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In Ayurveda *Kokilakshadi Kashaya*m is mentioned in *Vatarakta Rogadhikara*. *Kokilakshadi Kashaya*m it has *Kokilaksha*, *Guduchi*, and *pippali churna* as *Prakshepa dravya*[7].Kokilaksha (*Talmakhana)* has *Madhura Rasa* and *Guru* and *Snigdha Gunas*. It has sheet *Virya* and *Madhur vipak*. It pacifies *Vata* and *Pitta doshas* and is kno wn to have diuretic properties.[8] *Guduchi* is mentioned as *Rasayandravya* in *Samhitas*. It is *Tridosh Shamak*, *Deepniya* and apetiser. [9]It is known to have Anti-inflammatory, Anti Arthritic, and Anti osteoporotic activity.[10] Hence it can work on *VataRakta*. *Pippali* has the property of *tridosha* shamak. [11] It also has anti-inflammatory and immunomodulatory activity.In keeping view of this, *Kokilakshadi Kashaya*m is chosen for the patient of *VataRakta* for this study. *Kaishore Guggulu* is given for *VataRakta* in National List of Essential Ayush Medicines (NLEAM) 2022. It is also given in *VataRakta Rogadhikar* in Ayurvedic texts.[12]

VIII. TRIAL STATUS

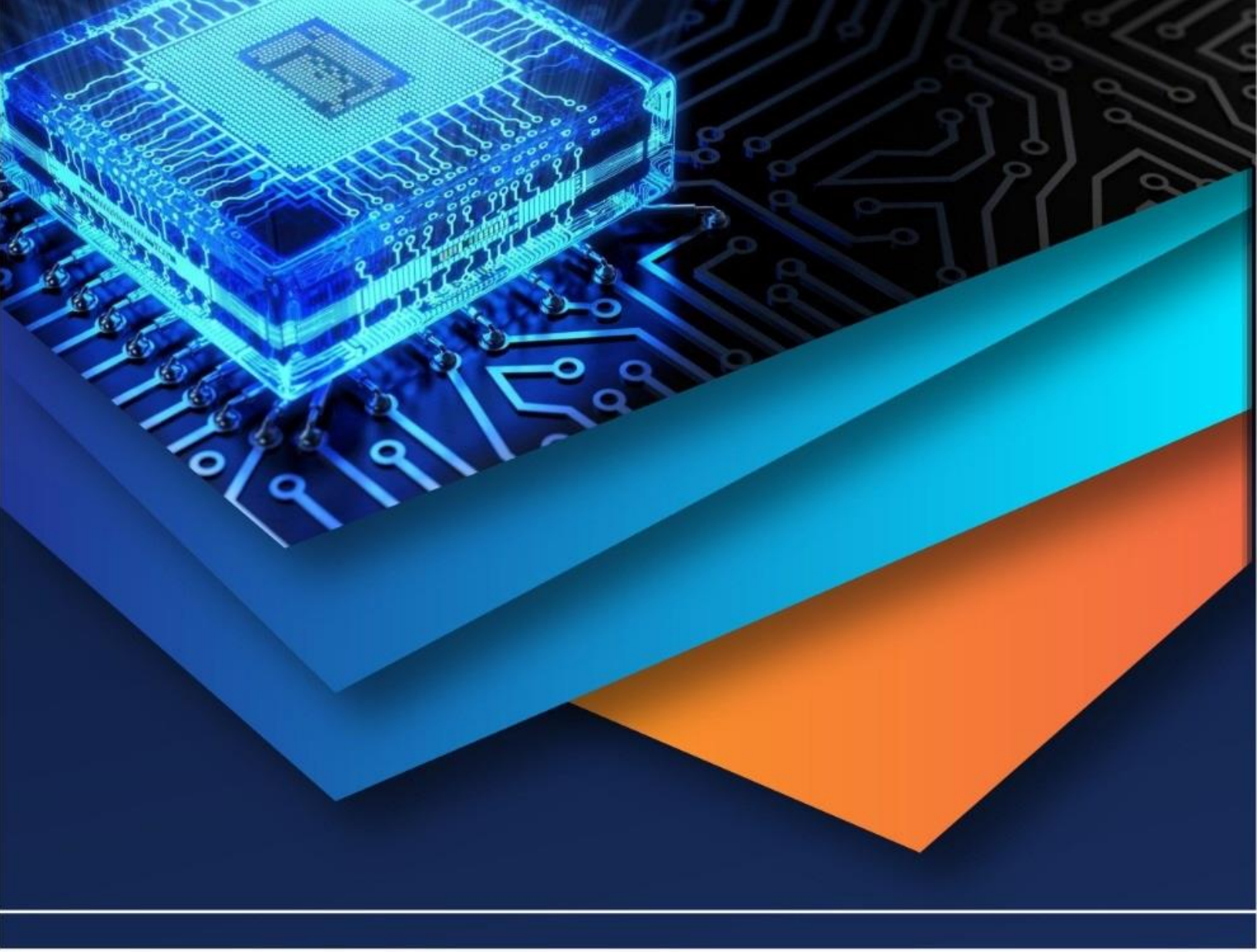
The study is recruiting patients.

1) *Declarations:* Ethics approval and Consent to Participate: The study was approved by the Ethics committee of Shri Krishna Ayush University, Kurukshetra (No. SKAU/ Acad/2022/6740)
2) *Financial Implications:* The financial allotment shall be given by Shri Krishna Ayush University for the study will be utilized and will be completed within the financial limit supplied by the institute.
3) *Followed Guidelines:* The usual guidelines for clinical trials are being followed in the conduct of this trial. (Declaration of Helsinki).

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