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Comparative Effectiveness of Akika Pishti with Jatamansyadi Kwath in the Management of Raktagata Vata (Essential Hypertension) - Study Protocol for an Open Labelled Randomized Controlled Trial

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Abstract: ***Background- Ayurveda has described several treatment modalities regarding the treatment of Raktagata Vata including the usage of herbo-mineral formulations, yoga and lifestyle modifications. The purpose of this study is to compare the efficacy of a mineral formulation Akika Pishti with Jatamansyadi kwath in the treatment of Raktagata Vata patients. Despite the fact that there are many formulations, no research has been done to demonstrate Akika Pishti's effectiveness in treating Raktagata vata.***
Methods and design- In a prospective, open labelled, randomized controlled trial, 60 patients, between 18 and 45 years, diagnosed with Raktagata Vata, presenting with cardinal features of Raktagata Vata as presented in Ayurvedic texts, two groups will be randomly assigned. In Group one, the patients will be given Akika Pishti and in Group two, patients will be given Jatamansyadi kwatha. Guidelines regarding Pathya-apathya will be given to both the groups. The course of treatment will last for 28 days for both groups. Outcomes will be evaluated on 7th, 14th, 21st & 28th (During treatment) & 42nd day (post-treatment).
Result: The primary result will be assessed by checking the grading of the cardinal symptoms of Raktagata Vata mentioned in Ayurvedic texts. Secondary outcome will check for reduction in systolic and diastolic blood pressure and improvement in quality of life of the patient.
Conclusion: This trial compares the efficacy of Akika Pishti with Jatamansyadi kwath in the patients of Raktagata Vata. Akika Pishti is envisioned to improve the symptoms of Raktagata Vata, thus proving to be effective in management of patients of Raktagata Vata.
Keywords: Akika Pishti, Jatamansyadi Kwath, Raktagata Vata, Randomized trial.

I. INTRODUCTION

A. Background and Rationale

The disease Hypertension is referred to as the "Silent" or "Hidden Killer" in medical terminology because of the End organ (*Tri marmas*) damages that have disastrous and dangerous effects on humans and ultimately result in death. Over 95% of Hypertension is categorized under essential hypertension. Hypertension may be defined clinically as the level of blood pressure at which the institution of therapy reduces blood pressure-related morbidity and mortality [1]. The term essential hypertension is used when elevated blood pressure cannot be promptly attributed to systemic dysfunction. Only routine medical examination or hospital visits for patients with serious complications like angina or myocardial infarction can detect it. Although there are no direct references to Hypertension in *Ayurvedic* scriptures. The disease and its treatment can be understood in light of *Ayurveda's* fundamental principles. According to *Acharya Charak*, if a *Vaidya* is unable to identify a disease, it should be treated according to its *Prakruti, Samutthan*

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and *Adhishthana* [2]. Many academics compared the following *Ayurvedic* diseases with hypertension: *Kaphapita Avruta Vyana Vata*, *Sirogata Vata*, *Dhamani Pratichaya*, *Dhamani Kathinya*, *Vyan Vayu Vaishamya* etc. Hypertension can also be correlated with *Raktagata Vata* as its symptoms like *Padayoh Daaha*, *Twak Sphota*, *Sotha*, *Klama*, *Raktasrava*, *Spandan* [3] more closely resemble the symptoms of Essential Hypertension. In Hypertension, the Heart (*hridaya*), one of *Trimarma*, the *Adhisthan* of *Chetas* (*Manas*), *Vyana Vayu* and *Sadhaka Pitta* are mainly affected. *Pitta Vardhak Aahar Vihar* causes *pittadushti* which leads to the vitiation of *Rakta dhatu* and *Raktadhatu* is the primary *Dushya* involved in *Raktagata Vata*. Vitiation of *vata dosha* by *viruddha aahar vihar sevan* and *vatavardhak nidans* as mentioned in *Charak chikitsa* 28th chapter[4] hinders the normal functioning of *vyan vayu*, whose *karma* is to circulate the body fluids throughout the body [5]. For which there will be abnormal circulation of body fluids which can be correlated with the increase in cardiac output, which ultimately leads to an increase in blood pressure [6]. Blood pressure continues to increase with age and in those >65 years the prevalence is approximately 60%. It is responsible for 50% of strokes and 25% of IHD as it is a major risk factor for both [7].

B. Trial design

This will be a prospective, randomized, open labelled, parallel group, double arm study on the diagnosed cases of Essential hypertension. The eligible volunteers who are enrolled will be randomized and allocated to two study arms (intervention group and control group) after obtaining signed informed consent. This study is designed in accordance with standard operating procedures for clinical trials (Declaration of Helsinki) following the ethical standards. The study has been approved by Institutional Ethics Committee of this institute and registered in CTRI [identifier - CTRI/2024/07/069945] prospectively. The trial is currently in the hiring stage. The medication was prepared from Shri Krishna *Ayush* Pharmacy that supplied quality control reports for two different medications.

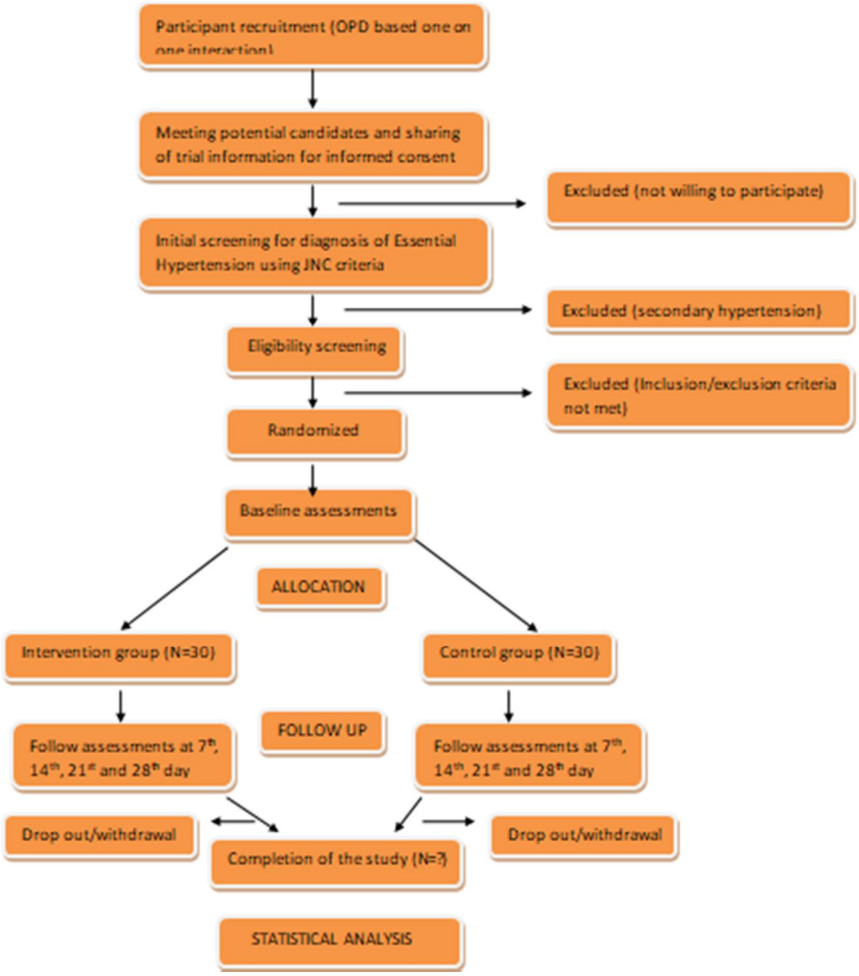


Fig 1: study flow chart

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II. METHODS

A. *Intervention*

Patients are assigned randomly to Groups A and B in a 1:1 ratio through a computer generated randomization sequence. Following randomization, patients in Group A, each Patient will be advised for taking *Akika pishti* in the dose of 250 mg with *madhu* twice daily for 28 days. Patients in Group B will be advised to take *Jatamansyadi kwath* with *madhu* twice daily for 28 days. Contents of *Akika pishti* and *Jatamansyadi kwath* are listed below:

Contents of *Akika pishti* [8]

a. *Suddha Akika bhasma*

b. *Gulaab jal* (Rose water)

Table no: 1 - Contents of *Jatamansyadi kwatha* [9]

Sr no	Drug name	Botanical name	Quantity	Parts used
1	*Jatamansi*	Nardostachys jatamansi	42 gm	Rhizome
2	*Vruhat ela*	Amomum subulatum	14 gm	Seed
3	*Rakta chandan*	Pterocarpus santalinus	14 gm	Heart wood
4	*Ashwaagandha*	Withania somnifera	14 gm	Root
5	*Parasika yavani*	Hyoscyamus niger	7 gm	Seed

B. *Eligibility*

1) Inclusion criteria*:* Patients of either gender with the age group of 18-45 years presented with cardinal features of *Raktagata Vata* as described in Ayurvedic texts with pre hypertension and stage 1 hypertension as mentioned in JNC 8 criteria, randomly selected, who are willing and able to participate in the study and provide written informed consent will be included in the study

2) Exclusion criteria: Patient below 18 years and above 45 years of age; Patient with SBP ≥160 mmHg, DBP ≥100 mmHg; secondary Hypertension (Chronic kidney disease, Hypothyroidism, Hyperthyroidism, Hyperaldosteronism, Uncontrolled diabetes mellitus with HbA1c ≥8%); patient taking steroids, oral contraceptive pills and estrogen replacement therapy; patient having systemic/serious complication of Cardio-vascular/Cerebro-vascular/ Renal system; Patient having an illness such as Ischemic heart disease, Chronic renal failure etc; any type of malignancy will be excluded. Alcoholics and any other drug abusers and the patient who has a history of hypersensitivity to the trial drug or any of its ingredients will also be excluded.

C. *Screening, Consent*

Apparently healthy volunteers (18-45 years) with already diagnosed and freshly diagnosed essential hypertension (Grade 1) as per JNC criteria will be included in the study. The research scholar will collect written informed consent from each participant prior to screening. The patient information sheet will be given to the participant containing details of the study in English/Hindi language whichever will be best suited and the patient will be instructed to go through it to discuss any query. The patient will be given sufficient time to take voluntary participation in the study. When the patient will be fully satisfied with the various aspects of the study, he/she will be asked to sign the consent form. Participant will be screened extensively for eligibility and upon determining eligibility they will be enrolled in the study following randomization procedure. Then the participants will be followed up at their predetermined time points till the completion of study period.

D. *Participant Timeline*

The trial consists of a 28 days trial with a follow up on every 7th day and all the patients will be evaluated for subjective and objective measures by the research scholar as per the schedule. Participants will visit the scholar 4 times during the trial and 2 times after the completion of trial. On initial visit after providing participant information sheet (PIS) and obtaining the written informed consent, the scholar will proceed for screening. After screening for eligibility criteria, laboratory investigations and ECG will be carried out to exclude other associated disease. Diagnosis of essential hypertension will be made by JNC criteria. Complete medical history will be taken by the scholar which will include patient's demographics, past and present illness, drug history with any surgical procedures if done before. Complete systemic examination will be done to assess the vitals. Ayurveda based basic clinical examinations such as *Ashtavidha* and *Dasavidha pariksha* will also be carried out.

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E. Clinical Outcomes

Primary outcomes measures will be assessed by checking the grading of the cardinal symptoms of *Raktagata vata* mentioned in *Ayurvedic* texts. Results will be assessed on 7th, 14th, 21st & 28th (During treatment) & 42nd and 56th day (post-treatment). The improvement in *Raktagata vata's* signs & symptoms mentioned in *Ayurvedic* texts will be used to evaluate the outcome. To establish the results statistically following grading will be noted for each sign & symptom. Here the grading is taken from the previous research work done of scholar Atul Kale from IPGT&R, JAMNAGAR [10] .

Secondary outcomes measures will check for improvement in Systolic and diastolic BP and quality of life of the patient.

Table no 2: Assessment Criteria (Subjective)

Sr no.	Symptoms	Grading
1	*Akshirag* (redness of eyes)	
	Nil	0
	Rarely and mild redness remains for small duration	1
	Frequently and moderate/mild redness remains present for 2 -3 hrs	2
	Often moderate/severe redness remains for a longer duration	3
	Continuous and moderate/severe redness nearly always present	4
2	*Santap* (burning sensation)	
	Nil	0
	A rare feeling of hotness in the head only does not disturb functions and daily activities relieved by cold application	1
	Frequent feeling of hotness in the head only disturbs functions but not daily activities relieved by cold application	2
	Frequent feeling of hotness all over the body disturbs functions and daily activities both require medication	3
	Continuous feeling of hotness all over the Body	4
3	*Shirahshool* (headache)	
	Nil	0
	Rarely Headache relieved without medication	1
	Frequently Headache relives by rest doesn't disturb daily activities	2
	Frequently severe Headache disturbs daily activities require medication	3
	Continuous/severe Headache disturbs sleep and daily activities and also not managed by the medication	4
4	*Klama* (fatigue without exertion)	
	Nil	0
	Rarely feeling of tiredness without any Exertion	1
	Rarely feeling of tiredness without any exertion with the inability to concentrate	2
	Frequently feeling tiredness without any exertion with the inability to concentrate	3
	Continuous feeling of tiredness without any exertion with the inability to concentrate	4
5	*Arati* (irritation)	
	Nil	0
	Rarely irritation of the mind, by major provocation and for a very short duration	1
	Rarely irritation of the mind by moderate to major provocation for a long duration	2
	Often irritation of the mind by mild to major provocation for a short duration	3
	Continuous irritation of the mind by any Provocation	4
6	*Nidra*	
	Sound Sleep	0
	Disturbed Sleep Wake up 1-2 times a night (*Khandita Nidra*)	1

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	Difficult-to-onset Sleep remains disturbed in night (*Alpa Nidra*)	2
	Very little sleep of small intervals makes patient irritable (*Atialpa Nidra*)	3
	Not getting sleep without medicine (*Anidra*)	4
7	*Krodha prachurata*	
	Nil	0
	Rarely getting angry by major provocation and for very short duration	1
	Rarely angry by moderate to major provocation for long duration	2
	Often angry by mild to major provocation for short duration	3
	Continuous angry and irritable	4
8	*Sattva bala*	
	Pravara sattva - No need for consolation, can tolerate severe discomfort easily	0
	Madhyam sattva - Can tolerate any discomfort with the help of consolation by others.	1
	Avara sattva- Can't tolerate nominal discomfort also on any account	2

Withdrawal criteria: The patient with major ailment which needs the new line of treatment and having any Adverse Drug Reaction (ADR) will be withdrawn from the study. Also the patient not willing to participate further or want to terminate will be also withdrawn.

III. METHODS – ASSIGNMENT OF INTERVENTIONS

A. *Randomization and Allocation*

The sequence generation will be done with the help of computer generated random numbers with an allocation ratio 1:1. A predetermined computer generated randomization chart will be developed. As per the chart, the eligible participants will be randomized in the ratio of 1:1 to either receive *Akika pishti* or *Jatamnansyadi kwath*.

B. *Allocation Concealment and Blinding*

The document of randomization will not be disclosed to ensure concealment. The trial interventions will be seal packed properly in air tight container and will be given to patient according to randomization schedule. Both the intervention and trial drug will be known to participant and the research scholar. No blinding or masking should be applied.

IV. METHODS – DATA COLLECTION, MANAGEMENT AND ANALYSIS

A. *Data collection and Management*

The primary source of data will be through symptoms of the assessment criteria, systolic and diastolic blood pressure readings which will be measured during the visits. The data will be collected by the research scholar himself to procure a reliable data. The collected data will be recorded in the case record form (CRF). Consent forms and CRFs will be stored in the concerned department of this institute. Confidentiality of the patients would be maintained during the entire trial.

B. *Statistical Analysis*

The subjective and objective parameters will be analyzed. The 30 patents in every 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.

V. DISCUSSION

In this trial, the efficacy of *Akika Pishti* with *Jatamansyadi kwath* in the treatment of *Raktagata vata* is compared. Hypertension is responsible for 50% of strokes and 25% of IHD as it is a major risk factor for both. Increased salt intake, obesity, smoking, sedentary lifestyle and stress, all increase its prevalence. Hypertension often causes minimal symptoms and if not checked it can remain undiagnosed for years. Symptoms when present may be headache, vertigo and palpitations [11].The exact signs and symptoms of Essential hypertension are not known and is often diagnosed on routine checkups. In some cases, it can cause early morning headaches, dizziness, fatigue, palpitations & symptoms related to organ damage involving the heart, kidneys and eyes [12].

These can be compared to the symptoms of *Raktagata Vata* which are *Padayohdaha*, *Twak Sphota*, *Sotha*, *Klama*, *Raktasrava*, *Spandan*[3] etc. The condition worsens if the patient remains untreated. The repeated use of allopathic medications such as diuretics, beta-blockers and ACE inhibitors leads to other metabolic side effects in the body such as hypokalemia, dyslipidemia, impaired glucose tolerance, cough [13] etc. Keeping in view of the above limitations and side effects this study has been chosen to fill this gap of providing a safe and effective line of treatment as Ayurveda provides multiple formulations for this. In *Raktagata Vata*, *Rakta* is the main *Dushya* vitiated mainly by *Pitta* and *vata Dosha*. *Rakgata vata* is also discussed under *Vatavyadhi*. So, both *Rakta prasadak* and *Vatapitta shamak* drugs will be of benefit in this condition. *Akika bhasma* is *vata-pitta shamaka*, *hrudya* and *mastiska valakarak* [14]. The *Pishti Kalpana* itself is *raktapitta shamak* and *soumya* in nature [15]. *Akika pishti* is taken for management of *raktagata vata* as both the *rakta* and *vata dosha* will be pacified because of *pitta* and *vata* pacification. *Jatamansyadi Kwath* is indicated for *Uchha Raktachapa* in AFI [16].In *Jatamansyadi kwath*, *Jatamansi* is present predominantly there. It is *tikta*, *kashaya* and *madhur ras* predominant and *sheeta veerya* [17]. All these *kashaya tikta* and *madhur ras* are best for the treatment of *pitta dosha* which ultimately pacifies *raktadosha*. Similarly, *Ashwagandha* is *laghu* in nature and *tikta*, *mdhura ras* predominant along with *madhur vipak* [18]. So, it is *vata-pitta shamak*. It also acts as *rasayan*, *valya* and *vrumhaniya* in nature [19]. *Raktachandan* is *tikta*, *madhura rasa* predominant, *sheet veerya* and *raktapitta hara* [20]. So, it will pacify *pitta* and *raktadosha*. *Parasika yavani* is *ushna veerya* and main action is *vedana sthapan* [21]. So, the *Vata dosha* pacification occurs. *Vruhatela* is *kaphapitta nashak* and *raktashodhak* [22]. Hence, the drug plays an important role in the treatment of *Raktagata vata* and is selected for the study. So here an effort is made to see whether *akika pishti* or *jatamamsyadi kwath* is more effective in the management of *raktagata vata*.

VI. DECLARATIONS

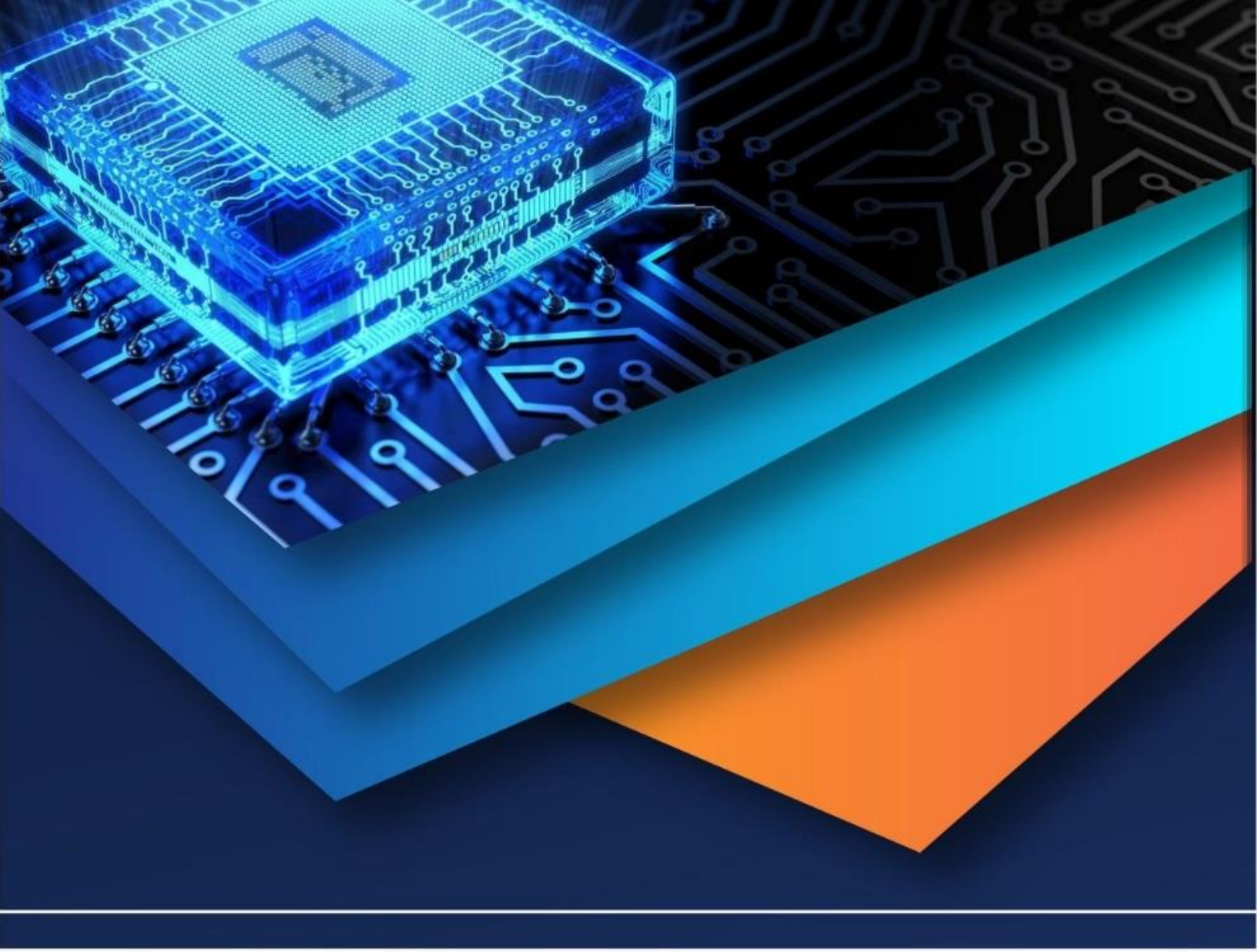
1) Ethics approval and Consent to Participate: The Ethics Committee of Shri Krishna Ayush University, Kurukshetra, accepted the study (SKAU/Acad/2024/10567).

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 provided by the institute.

3) Followed Guidelines: The common guidelines for clinical trials, known as the Declaration of Helsinki, are being followed in the conduct of this trial.

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