iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 13 **Issue:** V **Month of publication:** May 2025

DOI: https://doi.org/10.22214/ijraset.2025.71821

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue V May 2025- Available at www.ijraset.com

Comparative Effectiveness of Kanchnar guggulu and Yoga Practice in the Management of Subclinical Hypothyroidism. Study Protocol for a Randomized Open Labelled Comparative Clinical Trial

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Abstract: Background : ***The common cause of hypothyroidism is the inability of thyroid gland to produce a sufficient amount of thyroid hormones. India has a high prevalence of hypothyroidism which is about 10%. In subclinical hypothyroidism, no treatment is advised. The aim of this study to evaluate the effectiveness of Yogapractice incomparison with kanchnar guggulu in the management of subclinical hypothyroidism.***

Methods And Design: This study will be a prospective, single-centered, a randomized open labelled comparative clinical trial. A total of 60 patients of age between 19 and 60 years, diagnosed with subclinical hypothyroidism, will be randomized into two groups. In group A, patients will be given kanchnar guggulu and in group B patients will be guided Yoga practice. Both groups will receive treatment for 60 days. Outcomes will be evaluated on the 30th days and 60th days. The primary outcome will be evaluated on the basis of improvement in the serum TSH level in significant range. Secondary outcomes will be evaluated on the basis of improvement in the lab values of Serum Cholesterol, Serum Triglyceride and Serum Creatinine & quality of life of patient will be improved.

Conclusion: This trial is the first to compare the effectiveness of kanchnar guggulu and Yoga practice in the management of subclinical hypothyroidism. Yoga practice is expected to improve the symptoms of subclinical hypothyroidism, thus proving to be effective in the management of patients with subclinical hypothyroidism.

Trial Registration: CTRI/2025/02/080040

Keywords: Subclinical Hypothyroidism, Randomized Trial, Kanchnar Guggulu.

I. BACKGROUND

Thyroid is one of the earliest endocrine gland to build up.[1]thyroid gland is located in the front of neck which produces two hormones thyroxin [T_4] and triiodothyronine [T_3]. These hormones play a major role in cell differentiation during development and help in maintaining thermogenic and metabolic homeostasis in the body. Subclinical hypothyroidismis characterized by a serum TSH above the upper reference limit with a normal free thyroxin (T_4) level. This is only applicable when the hypothalamic-pituitary thyroid axis is normal. Usually it runs a chronic course along with slow and insidious onset. At times patients are accidentally diagnosed when they come to seek treatment of other related problems. Subclinical hypothyroidism refers to bio chemical evidence of thyroid hormone deficiency in patients who have few or no apparent clinical features of hypothyroidism. [2]The phase of compensation is when thyroid hormone levels are maintained by the rise in TSH. Although some patients may have minor symptoms, this state is called Subclinical hypothyroidism.[3]Subclinical hypothyroidism is either asymptomatic or present with symptoms like puffiness of face and eyelids, bilateral periorbital oedema, dry skin and coarse skin, breathlessness, cold intolerance, hoarseness of voice, constipation, weight gain, fatigue, body ache, hair fall along with impaired menstrual cycle.[4] The prevalence of hypothyroidism in the developed world is about 4-5%[5] and that of subclinical hypothyroidism is about 4-15%[6]. India has a high prevalence of hypothyroidism, which is about 10%. It is much more common in females than in males.[7]This study will explore all ayurvedic literature, including brihadtrayi,laghutrayi, and nighantu, as well as modern textbooks.

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We will check google scholar, pubmed, scopus, articles, and research papers for relevant information regarding the subject. Though there is no direct description of this disease in ayurvedic text, there is a description in ashtanga hridyam that if the vaidya does not know the disease name, he can treat the disease according to its prakriti, adhisthan, bheda and hetu.[8] According to ayurveda, the metabolic processes of the body are under the control of jatharagni, bhutagni, dhatvagni and doshas. The symptoms of subclinical hypothyroidism are developed due to alteration of metabolic activity; which according to ayurveda, can be hypothesized- vitiation of mainly kapha dosha, rasdhatvagni and vitiated vata due to margavarodha by kapha.[9] Vitiation of rasa dhatu and kapha doshas along with vitiation of vata dosha can produce symptoms of subclinical hypothyroidism. The clinical picture of the disease shows the dominance of kapha dosha. The majority of the nanatmajaroga of kapha dosha[10] such as alasya (laziness/lethargy), nindra-adhikya (hypersomnia), tandra (drowsiness), apakti (indigestion), galganda (goitre), gurugatrata (body heaviness), balasak (asthenia), shwetabhasta (pallor), sheetagnita (impaired digestion), etc. Can be included as a signs and symptoms of subclinical hypothyroidism. Also, dushti of rasadhatu plays a major role in pathogenesis. Many of rasajavikaras which have been mentioned in ayurvedic text[11] are similar to the clinical features of subclinical hypothyroidism such as gaurav (heaviness), tandra (drowsiness/lassitude), pandutavam (pallor), klabya (impotence), agninasha (loss of digestive power), sada (exhaustion or tiredness of body), ashradha (disinclination of food).

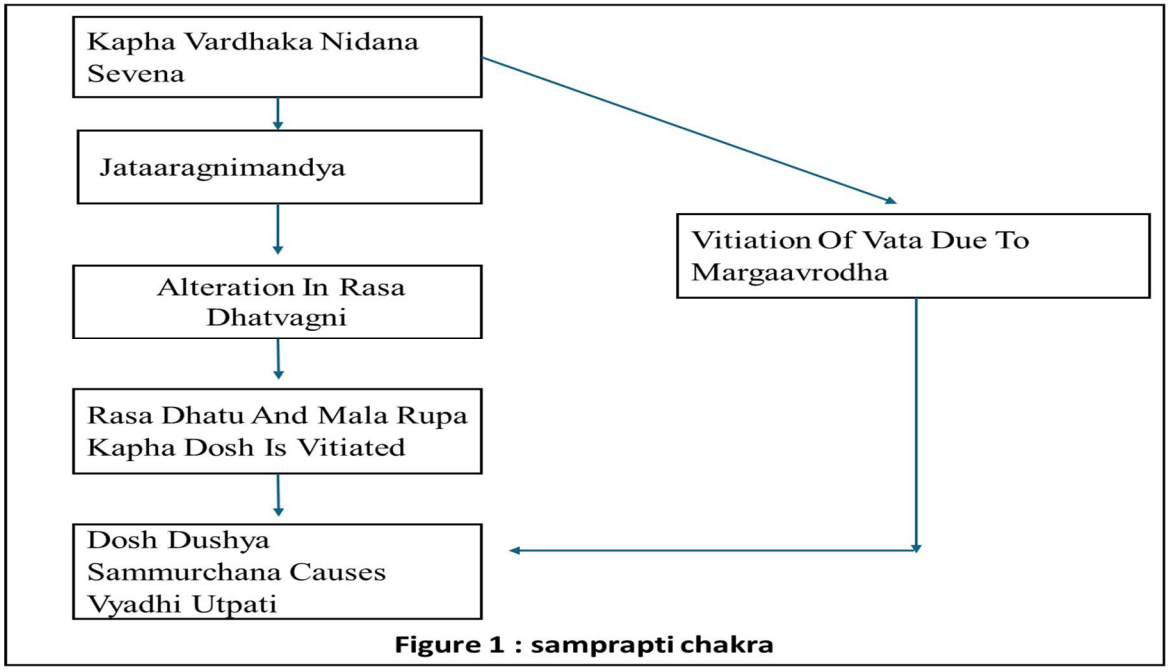


Figure 1 : samprapti chakra

So, hypothyroidism can be considered as anuktavikara and discussed under kapha dushti and rasdhatwagnimandyajnaya disorder by comparing its signs and symptoms to ayurvedic terminologies.

II. METHODOLOGY

1) *Patients:* Patients fulfilling the following criteria shall be included:-Newly diagnosed cases of subclinical hypothyroidism with TSH ranging from 5.5 to10uIU/ml. Patients of subclinical hypothyroidism, irrespective of sex, religion, profession, etc. Patients withan age limit of 19-60 years. Patients of Subclinical hypothyroidism willing to take ayurvedic medicine and sign the consent form.

Patients shall be excluded for the following criteria:-Patients having ages below 19 years and more than 60 years. Patient suffering from primary hypothyroidism, and secondary hypothyroidism. Patients with hyperthyroidism, neoplasia, toxic goitre, and who have undergone anytype of thyroid surgery. Patient taking aknown drug to alter thyroid hormone level (eg. amiodarone). Pregnant ladies andlactating mothers.Patients having anyother major complicated diseases like cardiac disease, renal failure, malignant disease, thyrotoxicosis& other systemic disorders TPO(Thyroid peroxidase) antibodies positive. Taking OCP(oralcontraceptive pills) for longer duration. Patient who take saindhavlavan or rocksalt should not beincluded in trial, but after 3 monthes ofintroducing the iodinised salt if TSH falls between 4- 10uIU/ml,than will be included in trial. Patient not willing to take the trial.

2) *Randomization:* Patients will be randomly assigned to interventional and control groups in a 1:1 ratio through a computer-generated randomization sequence. A patient will only be registered once and randomized once.
3) *Study Design:* In this single-centered randomized clinical trial all patients will be diagnosed on the basis of symptoms of hypothyroidism and TSH , T3, and T4 levels before randomization. after that interventional group will be guided *yoga* practice and the control group will receive 3gm of *kanchnar guggulu* in divided dose with lukewarmwater ½ hour after meal.

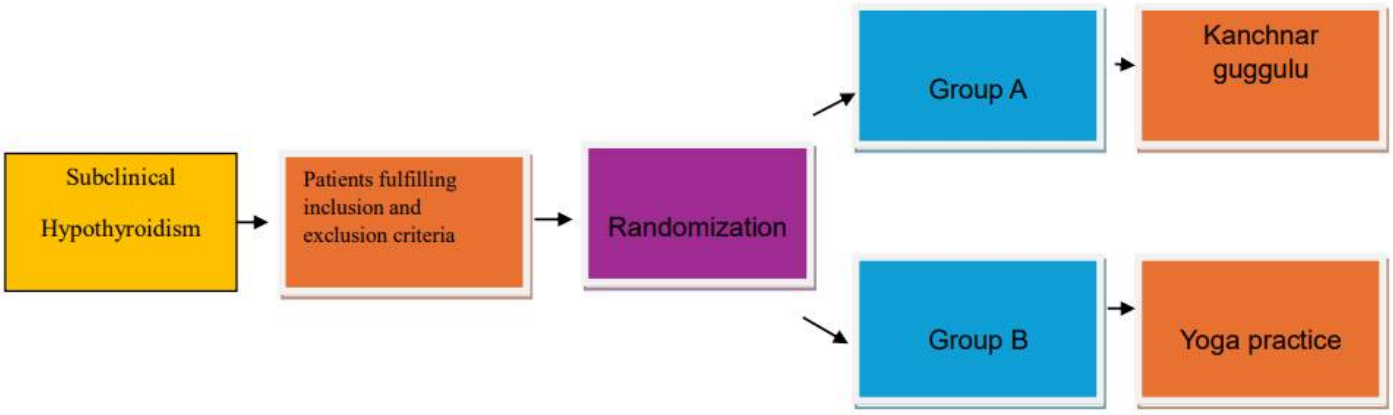


Figure 2: Study Design

4) *Outcome*: The primary outcome will be evaluated on the basis of improvement in the Serum TSH level in significant range. Secondary outcomes will be evaluated on the basis of improvement in the lab values of Serum cholesterol, Serum triglyceride and Serum creatinine & quality of life of patient will be improved.
5) *Objective Parameters*

S.No.	Parameters	Before Treatment	After Treatment
1.	TSH	✓	✓
2.	T3	✓	✓
3.	T4	✓	✓
4.	Serum cholesterol	✓	✓
5.	Serum triglyceride	✓	✓
6.	Serum creatinine	✓	✓
7.	Anti TPO	✓	×

Table No. 1

TSH , T3,T4, level will be investigated on the 30th and 60th days of trail and between the trail if needed. Objective parameters will be compare before & after the clinical trial.

6) *Assessment Criteria:* Pre and post follow up assessments will be carried out in all groups. The assessment of progress will be observed after 60 days.The evaluation will be done based on a Statistical analysis of the results thus obtained by using the statistical method.
7) *Interventions*

Interventional Group :*Yoga* Practice Duration- 40minutes

The patients in the study group will be guided as per following *Yoga* Practice:-

Sukshamavyayam(WarmUp) 3minutes

GreevaSanchalan(Neck Movement)	2minutes
Sarvangasan (Shoulder stand pose)	3minutes
Bhujangasan (Cobra Poses)	2minutes
Sequential (Repeat)	5minutes
Shavasan (Corpseposition)	1 Minutes
Kapalbhati Pranayama	10times
Anulomvilom	15times
Bhramri Pranayama	10times
Udgeeth Pranayama	10times
Ujjayi Pranayam	10 Times

Yoga Practice will be performed once in a day preferably morning time,empty stomach. study group will be guided regarding *yoga* practice as per the above schedule for 60 days.
Control Group: This group will receive *kanchnar guggulu.*

Table No. 2

Intervention	Dose	No. of patients	Route of Drug Administration	Duration
Kanchnar Guggulu	3 gm in divided dose with luke warmwater½ hour after meal.	30	Oral	60days

Sr.No.	Sanskritname	Botanical Name	Partused	Ratio
1	*Kanchnar*	Bauhinia Variegate(L.)Benth	Bark	480gm
2	*Haritaki*	Terminalia ChebulaRetz.	Fruit	96gm
3	*Bibhitaki*	Terminalia Bellerica	Fruits	96gm
4	*Amalaki*	Emblica Officinalis Gaertn.	Fruits	96gm
5	*Sunthi*	Zingiber Officinale(Rosc.)	Rhizomes	48gm
6	*Marica*	Piper Nigrum Linn.	Seeds	48gm
7	*Pippali*	Piper Longum Linn.	Fruits,	48gm
8	*Guggulu*	Commiphora Mukul Hook.	Resin	996gm
9	*Ela*	Elettaria Cardamomum (L.)Malon	Seed	12gm
10	*Twaka*	Cinnamomum Zeylanicum Blume	Bark	12gm
11	*Tejpatra*	Cinnamomum Tamala Nees	Leaf	12gm
12	*Varuna*	Crateva Magna (Lour.) Dc.	Stem, bark	48gm

The Drug Is A Combination Of Contents As Mentioned In Table No 3.

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8) *Statistics:* The analysis will be as per protocol analysis. The 30 patients in each group will be studied. The information gathered on the basis of the observations was subjected to statistical analysis using SPSS and MS Excel software in terms of Mean (X), Standard Deviation (S.D.) and Standard Error (S.E.). unpaired t-test will be carried out at $p<0.05$, $p<0.01$ and $p<0.001$ levels. The obtained results were interpreted as:

Insignificant - $P < 0.10$
Significant - $P < 0.05$, < 0.01
Highly Significant - $P < 0.001$.

III. DISCUSSION

This trial is the first to compare the effectiveness of *kanchnar guggulu* and *yoga* practice in the management of subclinical hypothyroidism. The common cause of hypothyroidism is the inability of thyroid gland to produce a sufficient amount of thyroid hormones. The symptoms of subclinical hypothyroidism are developed due to alteration of metabolic activity; it is lifelong therapy or no treatment given for subclinical hypothyroidism. Many studies show very little or no improvement in cognition, weight or quality of life in patients taking levothyroxine for the milder form of subclinical hypothyroidism. [12-13] In patients with subclinical hypothyroidism, 2.6% each year if Thyroperoxidase (TPO) antibodies are absent and 4.3% if they are present convert into clinical hypothyroidism every year.[14] As ayurveda emphasizes the treatment of preconditions (sanchya, prakopa, prasar, purvarupa), so that, the disease (vyadhiutpatti) does not progress to further stages. So, this study has been selected. According to ayurveda, Subclinical hypothyroidism can be considered as anuktavikara and discussed as kapha dushti,dhatwagnimandyajanyavhadhi. In hypothyroidism, the principal concern is to normalize the kapha dosha and restoration of agni. *Kanchnar guggulu* is a proven drug for subclinical hypothyroidism by previous research works. [15] Doshadushyasammurchana causes vyadhiutpati. Kanchnar guggulu is in gandmalarogadhikar also given for agnideepan in ayurvedic text.[16]*Yoga* is an ancient mind-body discipline that originated in india. *yoga* is considered safe, can be easily learnt and can be practiced both indoors and outdoors. *Yoga* can be practiced across all genders and age groups. *Yoga* is a discipline that includes body, breath, mind and behavior practices. It promotes a healthy lifestyle. *Yoga* brings many benefits to your overall health and well-being. it can balance your energy, increase flexibility, and relieve stress. Certain *yoga* poses are thought to balance out thyroids that are underactive. *Yoga* asanas such as sarvangasan, bhujangasan, followed by pranayama.[17][18][19][20][21][22] These poses will beconsidered throat-stimulating. They're thought to improve circulation and energy flow around the thyroid gland, stretch and strengthen the neck and activates the thyroid gland, that the improvement in the health of the entire subject domain. This will be achieved by regular practice of *yoga*. Hence, *yoga* practice and *kanchnar guggulu* will be selected for the study. Here, an effort is undertaken to determine which group, *yoga* practice or *kanchnar guggulu* is more effective for the management of subclinical hypothyroidism. The outcomes of the clinical trial will be essential in determining the practical applicability and effectiveness of these ayurvedic and *yoga* practice interventions in the management of subclinical hypothyroidism.

1) Trial Status: This Study Is Recruiting Patients.

2) Declaration

- Ethics Approval and Consent to the Participation: This study has been approved by the institutional ethics committee with No. (SKAU/Acad/2024/11976)
- Financial Implications: The financial allotment shall be given by Shri Krishna Ayush University for the study will be utilized and the trial will be completed within the financial limit provided by the institute.
- Followed Guidelines: The trial is conducted according to the common guidelines of clinical trials (Declaration of Helsinki).

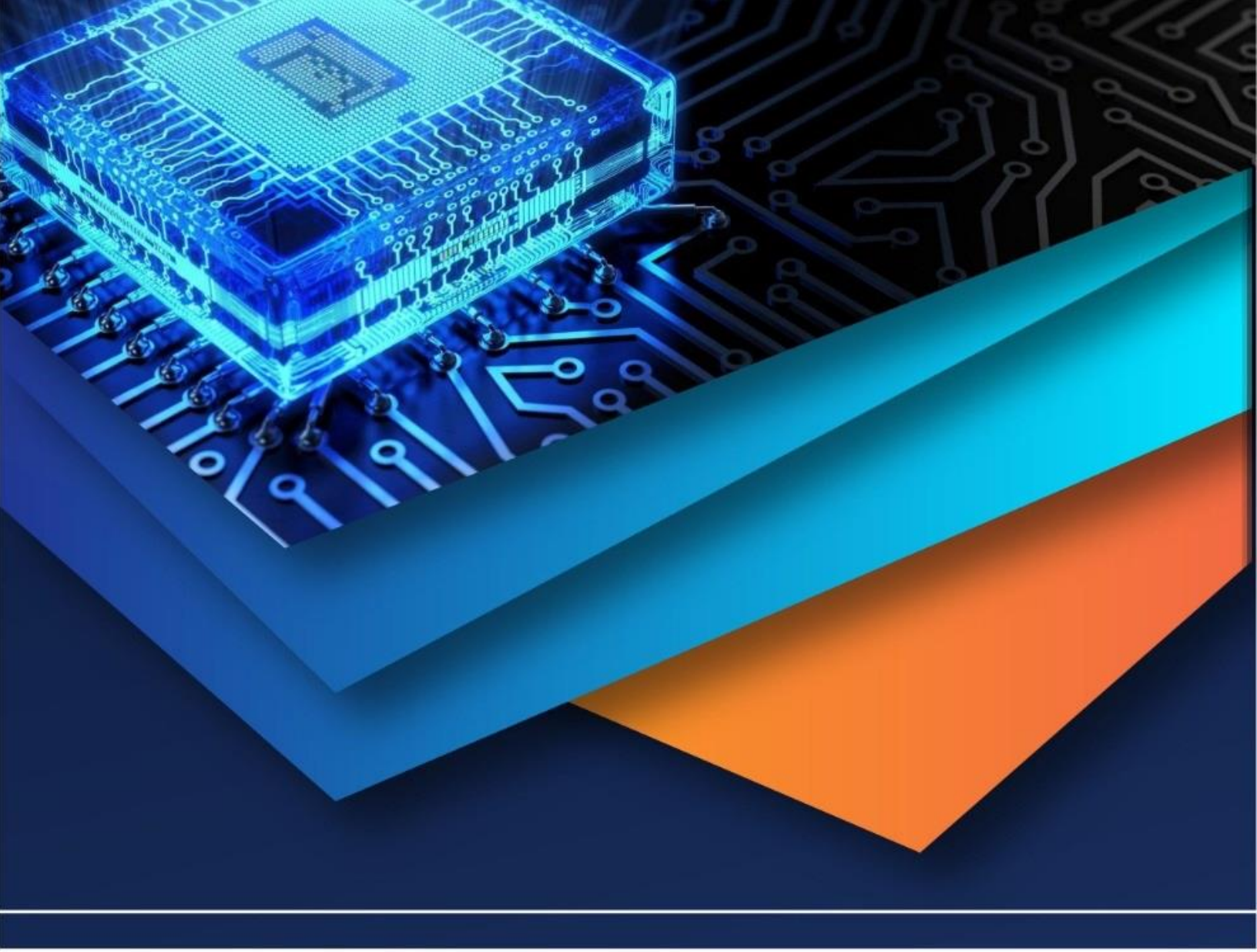
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