IJPSR (2025), Volume 16, Issue 5 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 08 December 2024; received in revised form, 28 December 2024; accepted, 31 December 2024; published 01 May 2025

COMPARATIVE STUDY ON SAFETY AND EFFICACY OF THE DECOCTIONS OF *SESAMUM INDICUM*, *NIGELLA SATIVA* AND ITS COMBINATION ON POLYCYSTIC OVARY SYNDROME

S. H. K. Deepthika [1], K. P. K. R. Karunagoda [* 2] and Pathirage Kamal Perera [* 3]

Department of Kaumarabhritya and Streeroga [1], Faculty of Indigenous Medicine, Gampaha Wickramarachchi University of Indigenous Medicine, Yakkala, Sri Lanka.
Department of Ayurveda Surgery [*2], ENT, Ophthalmology and Gynecology, Obstetrics and Pediatrics, Faculty of Indigenous Medicine, University of Colombo, Colombo, Sri Lanka.
Department of Ayurveda Pharmacology [*3], Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Colombo, Sri Lanka.

Keywords:

Polycystic ovary syndrome, *Nigella sativa*, *Sesamum indicum*, Hirsutism, *Acanthosis nigricans*

Correspondence to Author:
Pathirage Kamal Perera

Professor,
Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Colombo, Sri Lanka.

E-mail: kamalperera@fim.cmb.ac.lk

ABSTRACT: This study investigated the efficacy and safety of three herbal decoctions for managing Polycystic Ovary Syndrome (PCOS), a condition affecting 2–26% of women globally and considered incurable within allopathic medicine and offers symptomatic treatments. This randomized, single-blind clinical trial, conducted between February 2022 and June 2024, enrolled 90 PCOS patients diagnosed by the Rotterdam (2003) criteria. Participants were randomly allocated into three intervention groups: *Nigella sativa* (Arm I), *Sesamum indicum* (Arm II), and a combination of both (Arm III). Each group received 30 ml of the assigned decoction twice daily over three months. Clinical parameters were assessed using established grading scales, including androgenic alopecia, hirsutism, acne, and acanthosis nigricans. Additionally, ultrasound scans (USS) were performed pre- and post-treatment to evaluate changes in ovarian morphology. Results indicated a significant reduction in ovarian volume for Arms I (P=0.029) and II (P=0.008) and an increase in follicle size across all three arms. The number of participants with polycystic ovarian morphology significantly decreased in Arm I (P=0.016) and II (P=0.004). However, one-way ANOVA revealed no statistically significant differences between the three groups regarding subjective clinical symptoms or objective ultrasound parameters. The study concludes that all three interventions effectively regulate menstruation and enhance follicular maturity. Among the three, the combined therapy of *Nigella sativa* and *Sesamum indicum* (Arm III) demonstrated the most pronounced benefits. These findings suggest that *Nigella sativa* and *Sesamum indicum*, individually or in combination, hold potential as therapeutic options for PCOS management without any side effects.

INTRODUCTION: Polycystic Ovary Syndrome (PCOS) ranks as one of the most common endocrine diseases in women of reproductive age [1]. The prevalence of PCOS varies by ethnicity, yet most clinical evidence suggests it is about 6-7%.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.16(5).1300-07

This article can be accessed online on www.ijpsr.com

DOI link: https://doi.org/10.13040/IJPSR.0975-8232.16(5).1300-07

PCOS affects women of South Asian descent at an earlier age, with more severe symptoms and a more considerable prevalence [2].

Polycystic Ovary Syndrome is characterized by the appearance of multiple small cysts in the ovaries, menstrual irregularities, and signs of excess androgen production such as hirsutism (excess facial or body hair), male or female pattern balding (hair loss), acanthosis nigricans (skin discolorations), and acne. Regarding menstrual irregularity, menses may be irregular, oligo-menorrheic (reduced frequency of menstruation), or

amenorrheic (periods of six months or more without menstruation). In addition, PCOS is linked to obesity, insulin resistance, hypertension, elevated levels of lipids, and metabolic syndrome. A PCOS women with these high-risk features is more likely to get type II diabetes and cardiovascular diseases [3].

According to Ayurveda, PCOS can be mostly related to "*Pushpaghni Jataharini*," a disease mentioned in *Kashyapa Samhita* [4] and considered a disorder involving *Vata*, *Pitta*, *Kapha*, *Medas*, *Artavavahasrotas,* and *shukra/arthavadhatu,* and its cysts are similar to *Kaphaja Granthi (Granthi* refers to knotty elevation). According to *Ashtangahridaya* and *Susruta Samhita*, it refers to nodular or glandular swelling with a hard, knotty, and rough appearance [5].

According to allopathic medicine, PCOS is an incurable condition and suggested symptom-focused treatments, such as hormone therapy, *in-vitro* fertilization, embryo transfer, and gamete intra-fallopian transfer. However, these have not been 100% effective, have adverse effects, and are not readily accessible to everyone. Hence, finding new treatment options for PCOS is essential. This research study aimed to evaluate the effectiveness of three herbal decoctions for PCOS: *Nigella sativa* (Arm I), *Sesamum indicum* (Arm II), and a combination of the two (Arm III).

MATERIAL AND METHODS:

Study Area: This study was conducted in the Gynecology clinic of the National Ayurveda Teaching Hospital, Borella, from February 2022 to June 2024. Patients were selected from those seeking treatments for PCOS and subfertility.

Participants: Participation in this research is voluntary. Patient recruitment was done by screening for eligibility criteria (inclusion, exclusion and diagnostic criteria).

Inclusion Criteria: PCOS women diagnosed by Rotterdam (2003) diagnostic criteria [6] for women between 20 and 40 years are included.

Exclusion Criteria: To ensure correct clinical assessment, conditions other than PCOS, suffering from other diseases that cause the same similar signs and symptoms of PCOS. (Thyroid disorders, severe insulin resistance, androgen-secreting neoplasm, etc., were excluded.) Patients having disorders of the reproductive tract, such as tuberculosis, carcinoma, and congenital deformities of the reproductive tract and other chronic illnesses, such as cardiac disease and hypertension, etc. and patients who are already on other treatment regimens were excluded.

Ethical Approval: The Ethics Review Committee, Institute of Indigenous Medicine (ERCIIM), University of Colombo, Sri Lanka (ERC no: 19/85) granted ethics approval, and the specialty board – *Prasutitantra Streeroga* of the Postgraduate Institute of Indigenous Medicine, Colombo University, Sri Lanka - approved the study protocol.

Sample Size: In PCOS cases, 3 months of conventional treatment response is about 30%, according to clinical experience in the conventional group. In this clinical trial, I wished to test if a new therapeutic regimen can increase the response in PCOS patients to 60% with a power (1- b) of 80%. The type 1 error risk (2a) should be 5%. With 10% dropouts into account, 43 patients per group were included, resulting in a total of 129 patients being allocated.

Randomization: Participants were recruited randomly from the three arms. A randomization sequence was generated using an online randomization website. Each group was enrolled with an allocation ratio of 1:1:1.

Treatment Protocol:

TABLE 1: DRUG DOSAGE AND METHOD OF DRUG ADMINISTRATION

Arm	Study Drugs	Dose	Mode of administration	Route	Period of intervention
I	*Nigella sativa* decoction	30ml of Decoction	Morning and evening before meals	Oral	3 months
II	*Sesamum indicum* decoction	30ml of Decoction	Morning and evening before meals	Oral	3 months

III	*Nigella sativa* + *Sesamum indicum* decoction	30ml of Decoction	Morning and evening before meals	Oral	3 months

Participants in Arms I, II, and III received oral medication for twelve weeks. Drug dose and administration were carried out as in **Table 1.**

Follow-Up: Study participants were followed for three months.

Preparation of the Drugs: Decoctions were prepared according to one of the basic formulations of *Kwatha* mentioned in Ayurveda Pharmacopeia Part I [7].

Outcome Measurements:

Changes in PCOS-related Clinical Findings: Findings of day 12 Trans Abdominal Sonography (TAS) or Trans-Vaginal Sonography (TVS) (ovarian volume, Largest Follicle size and endometrial thickness). Assessment of clinical features by Rotterdam (2003) Diagnostic criteria were carried out before and after the treatment. Standard grading systems like the Global Acne grading System [8], Ferri-man-Gall -wey Scale [9], Sinclair Scale [10], and the Burke's quantitative scale [11] were used to assess those clinical features.

Safety Assessment: Each patient underwent hematological and biochemical investigations for safety assessment. FBS, AST/ALT, serum creatinine and GFR were taken before and after treatments.

RESULTS AND DISCUSSION: This randomized, single-blind comparative clinical trial was conducted from Feb 2022 to June 2024. There were several random clinical trials conducted using Ayurveda drugs for PCOS. However, this is the first trial to assess the main clinical signs of PCOS using standard scientifically evaluated questionnaires. According to scientifically calculated data, 129 samples were divided into three arms using a computerized random chart. Due to the COVID-19 pandemic, fuel shortage, and economic crisis periods, it could not allocate 43 patients per group. Thirty patients were allocated to Arm I; 33 patients were allocated to Arm II, and 30 patients were allocated to Arm III. Due to heavy bleeding, two patients from Arm II were deducted, and one patient from Arm I was not continued due to raised gastritis symptoms after consuming the drug. Ultimately, 29 patients for Arm I, 31 for Arm II and 30 for Arm III continued till the end of the intervention.

TABLE 2: DISTRIBUTION OF PATIENTS' DEMOGRAPHIC AND SOCIO-ECONOMIC CHARACTERISTICS BY TREATMENT GROUP

Characteristic		Arm I (n=29)		Arm II (n=31)		Arm III (n=30)		Total (n=90)	
		No.	%	No.	%	No.	%	No.	%
Age: Mean (SD)		28.7 (4.2)		27.5 (4.8)		26.1 (5.0)		27.4 (4.8)	
Age at Menarche: Mean (SD)		11.7 (1.4)		12.2 (1.2)		12.0 (1.4)		11.9 (1.3)	
Civil Status	Married	18	62.1	14	45.2	10	33.3	42	46.7
	Unmarried	11	37.9	17	54.8	20	66.7	48	53.3
Educational	Primary	1	3.4	2	6.5	1	3.3	4	4.4
Attainment	Secondary	10	34.5	19	61.3	14	46.7	43	47.8
	Tertiary	18	62.1	10	32.3	15	50	43	47.8
Employment status	Housewife	7	24.1	7	22.6	5	16.7	19	21.1
	Mental oriented	14	48.3	11	35.5	10	33.3	35	38.9
	Physical oriented	2	6.9	4	12.9	3	10	9	10.0
	Student	4	13.8	6	19.4	9	30	19	21.1
	Unemployed	2	6.9	3	9.7	3	10	8	8.9

The age of the patients in the three treatments was within the ranges of early twenties and late thirties. Significant deviations between the three treatments cannot be seen in the patient's age. Most of the patients in Arm II and Arm III were unmarried, whereas most in Arm I were married. Very few of the patients had up to primary education for all treatments. The majority of patients in Arm I group have got tertiary education while majority of patients in Arm II group have had secondary education. Most patients in all three groups have been doing mental-oriented jobs. The next highest number of patients in Arm I and II Treatments were housewives, while those in Arm II group were

students. The number of patients who are doing physically oriented jobs is very low in all Arms. The mean age of menarches of the patients was almost the same for all treatment groups.

Clinical Presentation of the Sample:

TABLE 3: DISTRIBUTION OF THE SYMPTOMS OF THE PATIENTS

Symptom	Yes		No		Total	
	No.	%	No.	%	No.	%
Hirsutism	75	83.3	15	16.7	90	100.0
Oligomenorrhea	74	82.2	16	17.8	90	100.0
Acanthosis nigricans	65	72.2	25	27.8	90	100.0
Acne	60	66.7	30	33.3	90	100.0
Boldness	54	60.0	36	40.0	90	100.0
Amenorrhea	16	17.8	74	82.2	90	100.0

The most common symptom shown by patients was hirsutism. It has been shown by 75 patients out of 90 (83.3 %). The next highly reported symptom was oligomenorrhea, which was mentioned by 74 patients out of 90 (82.2 %). The symptom recorded from the least number of patients was amenorrhea (17.8 %).

Assessment of USS Findings:

TABLE 4: DESCRIPTIVE STATISTICS AND TESTING THE TREATMENT EFFICACY FROM USS DATA

Treatment Group	Measurement	Before Treatment		After Treatment		t-statistic	p-value (one tail)
		Mean	SD	Mean	SD		
Arm I	Volume of left ovary	11.15	5.03	9.98	3.91	1.985	0.029*
	Volume of right ovary	11.45	5.74	10.06	4.83	1.648	0.056
	Endometrial thickness	6.33	1.94	6.32	2.08	0.034	0.487
	Largest follicle size	3.11	4.21	6.30	5.65	2.950	0.003*
Arm II	Volume of left ovary	12.33	5.67	10.74	4.10	1.676	0.052
	Volume of right ovary	11.89	3.59	9.96	3.03	2.595	0.008*
	Endometrial thickness	6.52	2.73	6.74	2.33	0.619	0.270
	Largest follicle size	2.71	4.11	7.07	6.76	5.212	0.000*
Arm III	Volume of left ovary	12.03	3.93	11.54	4.29	0.809	0.213
	Volume of right ovary	11.63	4.63	11.55	5.05	0.105	0.459
	Endometrial thickness	5.91	2.45	6.17	2.13	0.609	0.274
	Largest follicle size	2.33	4.89	7.82	6.78	4.991	0.000*

* Significant at 5% level SD: Standard Deviation.

Considering the paired t-test, in Arm I, there was a significant drop in the volume of the left ovary, while Arm II showed a significant drop in the right ovary. For all the groups there were significant increases of the largest follicle size after giving the respective treatment.

TABLE 5: TESTING THE TREATMENT EFFICACY FROM POLYCYSTIC OVARIES

Treatment Group	% difference of the absence of PCO after the treatment	p-value of the McNemar Test
Arm I	20.7	0.016*
Arm II	8.8	0.125
Arm III	26.7	0.004*

* Significant at 5% level

After the treatment, it shows a significant reduction in the number of patients with PCO by the ultrasound scan findings in Arm I (P = 0.016) and Arm III groups (P = 0.004).

TABLE 6: TESTING THE TREATMENT EFFICACY OF REGULAR MENSTRUATION FOR EACH TREATMENT GROUP

Treatment group	% difference of the patients with regular menstruation after the treatment	p-value of the McNemar Test
Arm I	21.4	0.016*
Arm II	18.5	0.032*
Arm III	40.7	0.001*

* Significant at 5% level

Looking at the p-values of the table, it can be concluded that a significantly greater number of patients' menstruation has been regular after giving for all the arms.

Comparison of the Treatments:

TABLE 7: ANOVA TEST FOR USS DATA

Measurement	Source of variance	Sum of Squares	Degrees of Freedom	Mean Square	F-Ratio	p-value
Volume of left ovary	Between Treatments	18.4	2	9.2	0.565	0.570
	Within Treatments	1,416.7	87	16.3		
	Total	1,435.1	89			
Volume of right ovary	Between Treatments	52.8	2	26.4	1.540	0.220
	Within Treatments	1,490.6	87	17.1		
	Total	1,543.4	89			
Endometrial thickness	Between Treatments	1.2	2	0.6	0.155	0.857
	Within Treatments	344.5	87	4.0		
	Total	345.8	89			
Largest follicle size	Between Treatments	86.0	2	43.0	1.442	0.242
	Within Treatments	2,595.1	87	29.8		
	Total	2,681.1	89			

Since, all the p-values are greater than 0.05, there is no sufficient statistical evidence to conclude that at least one average value on differences (before – after treatment) of treatment was not different from other treatments for every measurement. Hence, it is evident that there are no differences between the three arms concerning the volume of ovaries, endometrial thickness, and the largest follicle size.

TABLE 8: ANOVA – SUBTRACTED DATASET ON SIGNS AND SYMPTOMS

Measurement	Source of variance	Sum of Squares	Degrees of Freedom	Mean Square	F-Ratio	p-value
Hirsutism	Between Treatments	0.093	2	0.047	1.053	0.353
	Within Treatments	3.862	87	0.044		
	Total	3.956	89			
Acanthosis nigricans	Between Treatments	0.529	2	0.264	0.951	0.391
	Within Treatments	24.194	87	0.278		
	Total	24.722	89			
Acne	Between Treatments	0.538	2	0.269	0.324	0.724
	Within Treatments	72.362	87	0.832		
	Total	72.9	89			
Androgenic alopecia	Between Treatments	0.089	2	0.044	1.334	0.269
	Within Treatments	2.9	87	0.033		
	Total	2.989	89			

Since, all the p-values are greater than 0.05, there is no sufficient statistical evidence to conclude that at least one average score difference (before treatment – after treatment) of a treatment was not different from other treatments for all signs and symptoms. Hence, it is concluded that there are no differences between the three Arms with respect to hirsutism, acanthosis nigricans, acne and androgenic alopecia. As the p-value of the sign acne is less than 0.05, it can be concluded that there is a treatment effect on the treatment Arm II & III on reducing acne. However, it has not shown positive effectiveness in reducing hirsutism, acanthosis nigricans, and androgenic. Although allopathic treatments can relieve PCOS symptoms, the recurrence rate is substantial following drug withdrawal, resulting in an extensive financial burden for both patients and society. As a result, comprehensive research into PCOS is critical [12]. According to a prevalence study conducted in 2005-2006, Sri Lanka reported the highest symptom of oligo/amenorrhea (95%) and 11 women with hirsutism (5%) [13]. However, considering the present study, the most common symptom shown by patients **Table 3** was hirsutism. Seventy-five patients have shown it out of 90 (83.3 %). The following highly reported symptom was oligomenorrhea, which 74 patients mentioned out of 90 (82.2 %). As the tested sample, one-fourth of

the PCOS patients were with the constitution of *Pitta Kapha* (25.6%). The following highest number of patients' constitution was *Pitta* (22.2%). High *Pitta Kapha* and *Pitta* constitution could be attributed to the selected age range. *Pitta* and *Kapha* were the most prominent in this age range [14]. Some research has investigated the mechanisms by which weight gain and obesity contribute to the pathogenesis of PCOS via the lens of its three cardinal hallmarks of metabolic dysfunction, hyperandrogenism, and reproductive dysfunction, including the essential involvement of the insulin pathway [15].

Hence, Obesity/High BMI is a risk factor for PCOS. 42 patients in this study out of 90 were overweight and above in terms of their BMI values. The study focused on the primary outcome which was the return of regular periods in individuals with oligo/amenorrhea. Secondary outcome measures for PCOS were clinical presentations such as hirsutism, acanthosis nigricans, Acne, boldness, and ultrasound scan parameters. A significantly greater number of patients' menstruation has been regular after giving treatment in Arm I, Arm II and Arm III **Table 6.**

As ultrasound scan parameters, Arms I and II showed significant deduction of ovarian volume and all three Arms showed significant increases in the follicle size after giving the respective treatment **Table 4.** There was a significant drop in the number of patients with polycystic ovaries in the USS after the treatment in the Arm I and Arm II **Table 5.**

Since, the p-value of sign acne is less than 0.05, it can be concluded that there is a treatment effect in Arms II and III on reducing acne. But it has not been significantly effective in reducing hirsutism, acanthosis nigricans, and androgenic. All the p-values related to clinical signs of Arm I are more significant than 0.05. Hence it has to be concluded that there is no treatment effect of the treatment Arm I on reducing clinical signs of hirsutism, acanthosis nigricans, acne and androgenic alopecia. When comparing three Arms by one-way analysis of variance (ANOVA) tests, it was proved that there are no differences between the three Arms concerning the objective parameters (obtained from Ultrasound Scan) and the subjective parameters (Hirsutism, *Acanthosis nigricans*, Acne, Boldness). The Chi-Square test was also carried out to test the association between the three Arms, and insignificant results were obtained. The pregnancy rate in subfertility patients was not statistically measured in this study.

However, the highest pregnancy rate, 11.7%, was recorded from Arm I (*Nigella sativa* group), while Arm III recorded an 11.11% pregnancy rate. Serum creatinine, GFR, SGOT, SGPT and FBS were tested as safety routine investigations before and after the treatment. According to the p-values of the results, Arm II and Arm III have been positively effective in reducing FBS.

However, there were no significant changes for other assessments after giving the treatments. Due to insignificant changes, the safety of three decoctions was proven. Insulin resistance, the most common metabolic feature, is found in almost 35%-80% of PCOS women [16]. Insulin resistance is a major contributor to many obesity-related diseases [17].

Hence, PCOS is aggravated by obesity, primarily through worsening insulin resistance. A medicine that reduces weight and insulin resistance could benefit PCOS. Arm II and Arm III both show positive effects in reducing BMI and reducing FBS. Hence Arm II or Arm III could be taken as the best treatment options. There is scientifically provided evidence regarding the beneficial effects of sesame on body adiposity indices [18] and the significant positive effects on fasting blood glucose [19].

TABLE 9: SIGNS AND SYMPTOM EVALUATION ACCORDING TO ROTTERDAM CRITERIA

Positive effect shown Sign/Symptom	Arm I	Arm II	Arm III
Reduction of Polycystic appearance on USS	√ (P=0.016*)	-	√ (P=0.004*)
Improvement of mesesregularity	√ (P=0.016*)	√ (P=0.032*)	√ (P=0.001*)
Clinical reduction of hyperandrogenism (Only shown reduction of acne)	-	√ (P=0.019*)	√ (P=0.042*)

Arm I consist of *Nigella sativa* decoction, Arm II consists of *Sesamum indicum* decoction and Arm III consists of *Nigella sativa* and *Sesamum indicum* combined decoction. Considering all positive

effects of all parameters, Arm III (*Nigella sativa* + *Sesamum indicum* decoction) shows more positive effects. Hence, *Nigella sativa* and *Sesamum indicum* both can be used as single drugs and as combinations for PCOS conditions. *Sesamum indicum* identified as the better, most cost-effective herb for Sri Lankan PCOS patients among the three decoctions.

CONCLUSION: This study proves that all three arms improve follicular maturity and regulate menstruation significantly in PCOS cases. The USS reported the *Nigella sativa* treated arms significantly reduced PCO appearance, while the *Sesamum indicum* arm showed a significant clinical acne reduction. Considering the positive effects of all parameters, Arm III (*Nigella sativa* + *Sesamum indicum* decoction) significantly reduces PCOS appearance in USS, regularizing the menstruation and reducing some features related to hyperandrogenism. Hence, the study found that the combined preparation of *Nigella sativa* and *Sesamum indicum* showed a more significant effect on PCOS-related symptoms.

Recommendations: Some signs and symptoms, such as *Acanthosis nigricans*, Obesity, and Skin tags, appear due to long-term hormonal imbalances, and reducing these symptoms will take more time.

Considering the patient, the present clinical study period was three months, and it is not enough period to change the above symptoms. Therefore, long-term multi-center clinical trials are needed to observe such changes.

ACKNOWLEDGMENT: Our honored thanks to the Director of the National Ayurveda Teaching Hospital and all the staff of Stree Roga Clinic of NATH. We humbly thank all the participants in this study for their cooperation. Further, we thank Dr. Priyadarshana Dharmawardhane for his valuable help, cooperation, and guidance in data processing.

CONFLICTS OF INTEREST: There is no conflict of interest.

REFERENCES:

1. Carmina E and Lobo RA: Polycystic ovary syndrome (PCOS): arguably the most common endocrinopathy is associated with significant morbidity in women. J Clin Endocrinol Metab 1999; 84(6): 1897–9.
2. Royal College of Obstetricians and Gynecologists. Patient Information: Polycystic Ovary Syndrome [Internet]. London: Royal College of Obstetricians and Gynecologists; 2015 [cited 2019 Jan 5]. Available from: https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/gynaecology/pi-pcos.pdf.
3. Zhu T, Cui J and Goodarzi MO: Polycystic ovary syndrome and risk of type 2 diabetes, coronary heart disease, and stroke. Diabetes 2021; 70(2): 627–637.
4. Deepthika SHK and Wakkumbura HP: A literature review on Ayurvedic interpretation of polycystic ovarian syndrome based on Pushpaghni Rewati, a disease mentioned in Kashyapa Samhita. Ayurveda Sameeksha. 2016/2017; 2(10): 49–52.
5. Tewari PV: Ayurveda Prasuti-tantra Evam Stri-Roga. Golghar: Chaukhambha Orientalia 2000; 365.
6. Boyle J and Teede HJ: Polycystic ovary syndrome: an update. Focus Reprod Health 2012; 41(10): 752–6.
7. Anonymous: Ayurveda Pharmacopoeia. Vol. 1, Part I. Sri Lanka: Department of Ayurveda; 2006. p. 31.
8. Doshi A, Zaheer A and Stiller MJ: A comparison of current acne grading systems and a proposal of a novel system. Int J Dermatol 1997; 36(6): 416–8.
9. Ferriman DM and Gallwey JD: Clinical assessment of body hair growth in women. J Clin Endocrinol Metab 1961; 21(11): 1440–7.
10. Sinclair R, Jolley D, Mallari R and Magee J: The reliability of horizontally sectioned scalp biopsies in the diagnosis of chronic diffuse telogen hair loss in women. J Am Acad Dermatol 2004; 51: 189–99.
11. Burke JP, Hale DE, Hazuda HP and Stern MP: A quantitative scale of acanthosis nigricans. Diabetes Care 1999; 22: 1655–9.
12. Cai M, Ni Z and Yuan Z: Past and present: a bibliometric study on polycystic ovary syndrome. J Ovarian Res 2023; 16: 42.
13. Kumarapeli V, Seneviratne RDA, Wijeyaratne CN, Yapa RMSC and Dodampahala SH: A simple screening approach for assessing community prevalence and phenotype of polycystic ovary syndrome in a semiurban population in Sri Lanka. Am J Epidemiol 2008; 188(3): 321–8.
14. Tewari PV: Ayurveda Prasuti-tantra Evam Stri-Roga. Vol. 1. Varanasi: Chaukhambha Orientalia 2007; 39.
15. Barber TM and Franks S: Obesity and polycystic ovary syndrome. Clin Endocrinol (Oxf) 2021; 95(4): 531–41.
16. Carmina E and Lobo RA: Use of fasting blood to assess the prevalence of insulin resistance in women with polycystic ovary syndrome. Fertil Steril 2004; 82(3): 661–5.
17. Barber TM, Hanson P, Weickert MO and Franks S: Obesity and polycystic ovary syndrome: Implications for pathogenesis and novel management strategies. Clinical Medicine Insights: Reproductive Health 2019; 13: 1179558119874042.
18. Raeisi-Dehkordi H, Mohammadi M, Moghtaderi F and Salehi-Abargouei A: Do sesame seeds and their products affect body weight and composition? A systematic review and meta-analysis of controlled clinical trials. J Funct Foods 2018; 49:324–32.
19. Sohouli MH, Haghshenas N, Hernández-Ruiz Á and Shidfar F: Consumption of sesame seeds and sesame products has favorable effects on blood glucose levels but not on insulin resistance: A systematic review and meta-

analysis of controlled clinical trials. Phytother Res 2022; 36(3): 1126–34.

How to cite this article:
Deepthika SHK, Karunagoda KPKR and Perera PK: Comparative study on safety and efficacy of the decoctions of *Sesamum indicum*, *Nigella sativa* and its combination on polycystic ovary syndrome. Int J Pharm Sci & Res 2025; 16(5): 1300-07. doi: 10.13040/IJPSR.0975-8232.16(5).1300-07.