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NIGELLA SATIVA APPLICATIONS IN ALLERGIC DISEASE CONTROL: NARRATIVE REVIEW

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ABSTRACT

Introduction and purpose: Allergic diseases are an increasing global health problem. As standard therapies may have limited efficacy or adverse effects, interest in natural adjuncts such as *Nigella sativa* and its main bioactive compound, thymoquinone, has grown. This narrative review summarizes evidence from 2017-2026 on *N. sativa* in allergy control, focusing on clinically relevant mechanisms and therapeutic applications.

State of knowledge: *N. sativa* exerts broad anti-allergic effects through immunomodulatory and anti-inflammatory pathways. Mechanisms include mast cell stabilization, reduced eosinophilic inflammation, IgE downregulation, Th1/Th2 balance modulation, and inhibition of inflammatory signaling pathways. Clinical studies suggest benefits in allergic rhinitis with reduced symptom severity and frequency, and in asthma with improved symptom control and pulmonary function. Promising findings exist for atopic dermatitis, mainly in preclinical models. Safety data are generally favorable, though outcomes depend on formulation, dose, and duration.

Summary: *Nigella sativa* appears promising as an adjunct in allergic disease management, not a substitute for standard pharmacotherapy. Its value is supported by multi-target immunomodulatory activity and good tolerability. However, evidence is limited by heterogeneous preparations, small populations, and short follow-up. Further well-designed randomized controlled trials are needed to establish optimal dosing, standardization, and long-term efficacy.

KEYWORDS

Nigella Sativa, Thymoquinone, Rhinitis, Allergic, Asthma, Dermatitis, Atopic Immunomodulation

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Introduction

Allergic diseases, including allergic rhinitis, asthma, and atopic dermatitis, have seen a dramatic global rise, with more than 30% of the world's population experiencing some type of allergic reaction, pollen allergy being the most common. The rapid increase in the incidence of these disorders and symptoms is largely attributed to environmental shifts and the "hygiene hypothesis", which suggests that civilizational development, excessive hygiene, and the Western way of life results in reduced microbial exposure and an imbalanced immune system. [1] A critical clinical manifestation of this trend is the atopic march, a progression where early-life skin sensitization and atopy often evolve into respiratory conditions such as allergic rhinitis and bronchial asthma. [2]

In response to the limitations and side effects of conventional pharmacological treatments, there is a growing interest in evidence-based natural products like *Nigella sativa* (NS), commonly known as black cumin or "seed of blessing" in Arabic. [3] Historically, NS has been used in traditional medical systems, including Unani, Ayurvedic and Prophetic medicine. [4] Popular ancient physicians, such as Hippocrates or Avicenna, reported numerous therapeutic uses of this plant, utilizing NS to treat respiratory symptoms like shortness of breath, among others. [4,5] In the modern era, NS has transitioned from traditional lore into the realm of evidence-based medicine, with its applications validated through clinical trials and attributed primarily to its bioactive constituent, thymoquinone (TQ). [1,4,6]

The aim of this narrative review is to synthesize recent clinical findings and explore the molecular mechanisms that justify the applications of NS in modern allergy management, with focus on allergic rhinitis, asthma, and atopic dermatitis.

Phytochemistry: Thymoquinone

The therapeutic efficacy of *Nigella sativa* is ascribed to its unique phytochemical composition. Thymoquinone (2-isopropyl-5-methylbenzo-1,4-quinone) is the main bioactive constituent and its keto isomer functions as the pharmacologically active form responsible for the majority of observed clinical benefits. [7] There are other bioactive compounds present in NS such as nigellone (dithymoquinone), thymohydroquinone, carvacrol, and p-cymene, which work synergistically to enhance its anti-inflammatory profile. [1,5,6,8] TQ is a lipophilic molecule, which results in poor water solubility and suboptimal oral bioavailability, posing a significant challenge in its clinical application. [7,9] Consequently, standardized oil preparations are generally preferred over raw seed powders to ensure consistent absorption and to protect the molecules from rapid first-pass hepatic metabolism. [5,9,10]

Molecular Mechanisms of Anti-Allergic Action

The anti-allergic efficacy of *Nigella sativa* is derived from its ability to target multiple nodes of the inflammatory cascade, ranging from initial sensitization to chronic tissue remodeling. NS acts as a potent immunomodulator that, through the activity of its bioactive constituents, intervenes at the genomic and cellular levels to restore immune homeostasis. [6,11] The underlying molecular actions contributing to this systemic control are summarized in Table 1.

Table 1. Multitarget molecular mechanisms of *Nigella sativa* in allergy control.

Mechanism	Primary molecular action	Impact on allergic disease
Mast cell stabilization	Decreased histamine and β -glucuronidase release from activated mast cells. Reduction in the total number of mast cells. [6,12,13]	Alleviates acute symptoms like sneezing, nasal itching and wheezing. [14,11]
Cytokine modulation	Suppression of Th2 cytokines (IL-4, IL-5, IL-13) and elevation of Th1 cytokines (IFN- γ). [4,11]	Restores immune balance and reduces chronic mucosal inflammation. [4,11]
IgE regulation	Reduction of both total and allergen-specific serum IgE levels. [2, 15]	Prevents the primary sensitization and subsequent triggers of allergic flares. [6,14]
Eosinophil inhibition	Reduced eosinophil recruitment, infiltration and peroxidase activity. [1,6,11]	Decreases tissue damage, mucus hypersecretion, and airway remodeling. [11,16]
Signalling pathway modulation	Modulation of PI3k/Akt/NF- κ B pathway; upregulation of Nrf2/HO-1 axis. [6,7,13]	Provides a broad corticosteroid-like anti-inflammatory effect at the genetic level. [5,13]
Epithelial barrier regulation	Downregulation of p63 transcription factor, upregulation of claudin protein expression, and reducing periostin. [17]	Enhances epithelial barrier integrity and prevents tissue/remodeling/polypsis. [17]

Clinical Applications in Allergic Diseases

Numerous reports in the medical literature highlight the efficacy of *Nigella sativa* oil (NSO) and other thymoquinone-containing preparations in alleviating the symptoms of allergic diseases. In an experimental animal model of allergic rhinitis, a 28-day NSO treatment regimen reduced the frequency of symptoms such as sneezing and nasal rubbing. Although the standard glucocorticosteroid, mometasone furoate, provided better protection of nasal cilia and more effectively prevented chondrocyte hypertrophy, NSO demonstrated significant tissue-protective effects by markedly reducing eosinophilic infiltration and goblet cell hyperplasia

[14]. Similar protective mechanisms were observed with thymoquinone administration in chronic rhinosinusitis with nasal polyps, where it restored epithelial barrier integrity and mitigated tissue remodeling [17].

The translation of these preclinical mechanisms into human clinical trials has yielded significant therapeutic effects, particularly regarding the classic symptomatology of hay fever. A recent randomized, double-blind, placebo-controlled study investigated a 15-day supplementation protocol using standardized NSO containing 5% thymoquinone. The intervention successfully reduced both the severity and duration of burdensome clinical symptoms, including sneezing, pruritus, and nasal congestion. Clinical improvement was reflected in elevated satisfaction scores on the Patient Global Impression of Change (PGIC) scale. These subjective clinical benefits were directly corroborated by objective physiological parameters, including decreased serum IgE concentrations and peripheral blood eosinophil counts [6]. Data derived from select meta-analyses suggest the clinical superiority of *Nigella sativa* supplementation over conventional allergic rhinitis treatments in control groups. Pooled analyses demonstrate a significantly higher overall efficacy rate (OR = 4.24, 95% CI [2.57,7.27], $p < 0.00001$) alongside substantial improvements in general nasal symptoms, including rhinorrhea, sneezing, and pruritus (MD = -2.60, 95% CI [-2.82, -2.38], $p < 0.00001$) [18].

Nigella sativa (NS) and its active compounds, exerting both bronchodilatory and anti-inflammatory mechanisms, may play a multidirectional therapeutic role in the management of bronchial asthma [16]. Improvements in pulmonary function parameters, particularly the reduction in peak expiratory flow (PEF) variability and the increase in forced expiratory flow (FEF 25–75%), suggest that NS attenuates bronchial hyperresponsiveness and improves patency of the small airways, which are pivotal in asthma pathogenesis. This bronchodilatory effect is accompanied by a significant reduction in fractional exhaled nitric oxide (FeNO), a non-invasive biomarker of eosinophilic airway inflammation and disease activity. The decrease in FeNO values indicates that NS suppresses the inflammatory process in the respiratory tract, likely due to its immunomodulatory properties and the restoration of the Th1/Th2 lymphocyte subpopulation balance (e.g., via stimulation of IFN- γ secretion and suppression of IL-4). The impact on FeNO reduction appears more pronounced at a dose of 1 g compared to 2 g. This phenomenon may stem from a non-linear (biphasic) dose-response relationship, most likely associated with the complex mixture of bioactive compounds present in the whole seeds. Furthermore, the manifestation of greater clinical benefits following 12 weeks of continuous supplementation suggests that NS mitigates the chronic inflammatory processes responsible for airway wall remodeling [16].

The clinical significance of these mechanisms is validated by both meta-analyses and individual clinical trials, which indicate a favorable safety profile for NS as an adjunctive therapy in adult asthma. A quantitative assessment of clinical effects was conducted in a meta-analysis comprising four high-quality randomized controlled trials (RCTs). It demonstrated that NS supplementation significantly improves Asthma Control Test (ACT) scores compared to the control group (Std. MD = 0.50; 95% CI [0.11,0.88]; $p = 0.01$), exhibiting high consistency of results and no statistical heterogeneity ($I^2 = 0\%$). Improvements in pulmonary function parameters were also noted, including a significant increase in forced expiratory volume in one second (FEV1) (Std. MD = 1.84; 95% CI [0.07,3.60]; $p = 0.04$). Despite theoretical premises regarding Th1/Th2 pathway modulation, this meta-analysis did not reveal statistically significant changes in peak expiratory flow (PEF) or concentrations of key inflammatory cytokines, such as IL-4 and IFN- γ [19].

These findings are complemented by detailed observations from individual clinical trials. In a 4-week study evaluating *N. sativa* oil (NSO) supplementation, a particularly marked improvement in FEV1 was observed in patients with baseline impaired lung function (FEV1 < 80% of predicted value). Moreover, this study demonstrated a significant reduction in peripheral blood eosinophilia - a primary biomarker of inflammation in asthma - even though patients' total serum IgE concentrations remained unchanged [20].

The application of *N. sativa* also demonstrates high efficacy and a favorable safety profile in the treatment of various dermatological conditions, including eczema, acne vulgaris, vitiligo, psoriasis, and cutaneous leishmaniasis. Distinct clinical benefits have been observed regardless of the route of administration - both with topical treatment (in the form of oils, emulsions, or ointments) and systemic therapy (orally via capsules or extracts) [10].

The therapeutic potential of *N. sativa* appears particularly promising in the context of atopic dermatitis (AD). In *in vivo* studies utilizing a DNCB-induced AD animal model, both oral and topical administration of thymoquinone (TQ) effectively reversed the clinical manifestations of the disease. The therapy significantly reduced epidermal hypertrophy and inflammatory tissue edema, improving clinical severity scores to a level comparable with the effects of tacrolimus - a standard immunosuppressive drug. Furthermore, normalization of the total leukocyte count and a marked decrease in serum IgE concentration were demonstrated. TQ also downregulated the expression of key proinflammatory cytokines, such as IL-4, IL-5, and IFN- γ [2].

Safety Profile and Tolerability

The growing clinical interest in *Nigella sativa* (NS) has been accompanied by increasing attention to its toxicological and tolerability profile, which appears favorable in both preclinical and early human studies [21, 22, 23]. Available evidence indicates that orally administered NS preparations and thymoquinone-rich formulations are generally well tolerated when used within therapeutic ranges, with no serious adverse events reported in phase I human assessment [21].

Importantly, toxicological data suggest that thymoquinone has a relatively wide safety margin, although its toxicity is route-dependent, with oral administration being substantially safer than parenteral exposure. Subacute studies cited in recent toxicology reviews identified a no-observed-adverse-effect level (NOAEL) of approximately 10 mg/kg, supporting the concept that clinically relevant oral doses are unlikely to produce systemic toxicity under controlled conditions [22]. However, subchronic and chronic animal studies have indicated that high doses of NS fixed oil may cause mild toxicity, such as transient alterations in leukocyte and platelet counts, emphasizing the need for appropriate dosing [23].

From a clinical perspective, the hepatic and renal safety of *Nigella sativa* (NS) during long-term supplementation is a critical consideration. Clinical trials generally report a favorable safety profile with no severe adverse events, though some studies have noted minor gastrointestinal symptoms - such as bloating and nausea - and occasional, slight elevations in liver and kidney enzymes [23]. Despite these isolated fluctuations, a recent systematic review and meta-analysis confirms that NS does not significantly alter standard hepatic or renal biochemical parameters, demonstrating an absence of overt hepatotoxicity or nephrotoxicity in humans [24]. This robust safety profile is highly relevant for allergy-oriented applications and the management of chronic inflammatory conditions. In these contexts, NS can serve not only as a well-tolerated adjunct to standard pharmacotherapy but also as a multi-target agent with cytoprotective and anti-inflammatory potential that may minimize collateral tissue damage, although further clinical validation remains necessary [25].

Although systemic administration appears reassuring, topical NS formulations may still induce local irritation or hypersensitivity in susceptible individuals, particularly when highly concentrated oils are applied directly to compromised skin barriers; therefore, patch testing or cautious initial use may be justified in patients with atopic skin phenotypes [21]. Overall, the currently available literature supports NS as a relatively safe adjunctive intervention, but it also emphasizes the need for larger and longer randomized trials with standardized preparations to define dose-dependent adverse effects more precisely [21].

Discussion

The synthesized evidence suggests that *Nigella sativa* is an effective adjunct therapy in the management of allergic diseases, rather than a replacement for primary agents like antihistamines. Clinical observations indicate that adding NS to standard regimens - such as inhaled corticosteroids or immunotherapy - can enhance therapeutic outcomes and improve overall disease control. Furthermore, this combined approach may offer a "steroid-sparing" benefit, potentially allowing for lower doses of conventional pharmaceuticals and thereby reducing the incidence of side effects associated with the long-term use of corticosteroids or leukotriene receptor antagonists. [18] Although some high quality studies, including RCTs, have been conducted over the past several years, significant research gaps remain that must be addressed in order to translate these findings into standardized clinical practice. Table 2. includes RCTs and meta-analyses on the use of *Nigella sativa* in allergic diseases dating back to 2017 and aims to highlight their outcomes and limitations.

Table 2. Clinical and Preclinical Evidence for *Nigella sativa* Supplementation in Airway and Allergic Pathologies (2017–2025).

Study	Study type and sample size	Key results	Clinical implications	Major limitations
Salem AM, et al. (2017) [16]	Single-blind RCT. N = 76 adults with partly controlled asthma. Intervention: 1g/day (n = 26) vs 2g/day (n = 26) of whole ground seeds vs placebo (n = 24) for 12 weeks.	• 2 g/day dose: Significant increases in FEV1 (% predicted) and FEF25-75% at 6 and 12 weeks (P < .05). • Both doses: Significant improvement in ACT scores (P < .001) and PEF variability (P < .05). • Inflammatory markers: Significant decreases in FeNO and serum IgE, coupled with elevated anti-inflammatory serum IFN-gamma at 12 weeks (P < .05).	• Provides clinical proof that oral <i>Nigella sativa</i> can serve as an effective adjunctive controller alongside standard inhaled maintenance therapies. • Demonstrates a dual benefit: improving mechanical airway parameters while actively suppressing underlying Th2 systemic inflammation.	• Single-blind design leaves room for assessment or investigator bias. • Did not analyze localized airway microenvironments due to a lack of bronchoalveolar lavage (BAL) or induced sputum sampling.
Koshak A, et al. (2017) [20]	Double-blind RCT. N = 60 asthma patients. Intervention cohorts: NSO group - 500 mg 2xday of softgel capsules of cold pressed NSO with 0.7% Thymiquinone (n = 30) vs placebo group (n = 30) for 4-weeks.	• Asthma Control: NSO significantly improved mean ACT scores compared to placebo (21.1 ± 2.6 vs. 19.6 ± 3.7; P = .044). • Eosinophil Count: NSO led to a significant reduction in peripheral blood eosinophils (-50 cells/uL vs. +15 cells/uL in placebo; P = .013). • Lung Function: NSO produced an upward trend in FEV1 (% predicted), though this did not reach statistical significance (4% vs. 1%; P = .170).	• Validates the clinical utility of <i>Nigella sativa</i> oil as an oral adjunct therapy to improve subjective disease control scoring. • Provides direct, objective <i>in vivo</i> evidence that NSO suppresses systemic Th2-driven eosinophilic inflammation.	• Short study duration: A 4-week trial is insufficient to evaluate long-term maintenance or impacts on permanent airway remodeling. • Single-center design.
He T, et al. (2024) [19]	Systematic review and meta-analysis of RCTs. Data pool: 8 RCTs enrolled tracking <i>Nigella</i> species supplementation for allergic rhinitis.	• Overall Efficacy: Supplementation group achieved a significantly higher total effective treatment rate vs. controls (OR = 4.24; 95% CI (2.57, 7.27); P < .00001). • Symptom Scores: Pooled data across 3 trials proved superior reductions in total nasal symptoms (MD = -2.60; 95% CI [-2.82, -2.38]; P < .00001). • Safety Profile: Adverse events across 5 studies were mild, transient, and showed no statistical variance from placebo (OR = 1.01; P = .98).	• Delivers Level-1 evidence validating that <i>Nigella</i> species substantially outperform standard controls or placebos in alleviating upper airway allergic symptoms. • Establishes a highly favorable risk-to-benefit ratio, cementing its safety profile as an undistruptive adjunctive therapy.	• Design Heterogeneity: Included trials featured variable design qualities and mixed baseline interventions, which could affect data reliability. • Small Data Pool: Constrained by a low volume of total matching published RCTs (8 studies). • Taxonomical Grouping: Analyzed pooled <i>Nigella</i> spp. broadly (including <i>N. sativa</i> and <i>N. glandulina</i>) rather than focusing exclusively on one species.

Majeed A, et al. (2024) [6]	Double-blind RCT. N = 65 adults with allergic rhinitis. Intervention cohorts: NSO group (250 mg oil standardized to 5% TQ + 2.5 mg Piperine 2xday, $n = 33$) vs placebo group ($n = 32$) for a 15-day duration.	• Symptom Scores: NSO treatment led to highly significant, rapid reductions in Total Nasal Symptom Scores (TNSS) and Total Ocular Symptoms Scores (TOSS) vs. placebo ($P < .001$). • Disease Frequency: The duration, episodes, and daily frequency of AR attacks dropped substantially within 15 days ($P < .001$). • Immunological / Safety: Serum IgE levels trended downward but did not differ significantly from placebo. Safety panel (hepatic, renal, hematology, and metabolic) remained entirely unchanged.	• Establishes that low-dose (500 mg/day total) NSO is clinically highly potent when standardized to 5% Thymoquinone and paired with a bioavailability enhancer like Piperine. • Proves rapid onset of action (measurable symptom relief within 5 to 15 days) without causing systemic side effects.	• Highly restrictive sample cohort: The trial layout inadvertently excluded female participants, limiting the generalizability of the findings across sexes. • Short tracking window: A 15-day evaluation is too short to observe immune restructuring, explaining the lack of significant variance in systemic IgE levels. • Narrow geographic footprint.
Ghobadi H, et al. [26]	Preclinical Systematic Review and Meta-analysis of animal model experiments. Data Pool: 18 controlled laboratory animal studies. N = 502 animals.	• Cytokine Suppression: <i>N. sativa</i> and its active extracts led to a highly significant pooled reduction in classic Th2 driving cytokines: IL-4, IL-5, and IL-13, alongside the Th17-derived inflammatory cytokine IL-17. • Immunoglobulin Shift: Demonstrated a notable, systematic decrease in total IgE levels post-intervention. • Unchanged Markers: Systemic levels of IFN-gamma showed no statistically significant change following active intervention.	• Provides aggregated statistical verification of the raw molecular pathways behind the plant's action, confirming it acts as a broad-spectrum cytokine suppressor in active allergic airway diseases. • Shines a light on the specific therapeutic roles of individual isolated fractions like Thymoquinone, Thymol, Carvacrol, and alpha-hederin.	• Translational Barrier: Animal data from ovalbumin-induced frameworks cannot be directly extrapolated to describe human asthma pathology. • Conflict with Human Data: The finding of "unchanged" IFN-gamma directly contradicts human clinical data (such as Salem et al., 2017), indicating inter-species immunodynamic differences.

Abbreviations: ACT - Asthma Control Test; NSO - *Nigella sativa* oil; OR - odds ratio; CI - confidence interval; AR - allergic rhinitis.

Note: Italicized lower-case n denotes individual cohort/sub-sample size; capital N denotes cumulative study sample size.

Conclusions

Nigella sativa appears to be a promising adjunct in allergy management, with effects extending beyond symptomatic relief toward modulation of fundamental disease drivers, including immune polarization and barrier dysfunction. Its pleiotropic activity suggests particular relevance in early or mixed-phase allergic responses, where simultaneous targeting of inflammatory and structural pathways may offer advantages over single-target interventions.

The observed clinical benefits appear to depend on formulation quality, duration of administration, and potentially non-linear dose-response relationships, indicating that therapeutic outcomes cannot be generalized across all preparations. This underscores the importance of standardization, especially regarding thymoquinone content and bioavailability.

From a clinical perspective, NS may be best positioned within personalized or integrative treatment strategies, particularly in patients with suboptimal control or intolerance to conventional therapies. Its role in

modifying disease trajectory - such as influencing the atopic march - remains an intriguing but insufficiently explored area.

Despite promising findings, current evidence is limited by heterogeneity in study design, small sample sizes, and variability in formulations and dosing. The lack of standardized preparations and long-term data remains a significant barrier to routine clinical implementation. Future research should focus on large-scale, well-designed randomized controlled trials using standardized NS extracts to establish optimal dosing strategies, long-term safety, and precise clinical indications. Overall, *Nigella sativa* represents a valuable complementary approach in the integrated management of allergic diseases.

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