



DOSSIER · SUBSTANCE

Black Cumin (Nigella Sativa)

The database comprises works on **black cumin**. The research focuses on **anti-inflammatory** and **metabolism-related** effects. The most interesting finding: A considerable portion of the studies is preclinical, controlled human studies remain limited and methodologically heterogeneous.

1,858

STUDIES IN
TOTAL

232

IN HUMANS

95

OF WHICH
CONTROLLED

426

IN ANIMALS

375

IN THE LAB

Figures from the IHR study database · Last updated 2026-10-15

How to Read This Dossier

ESTABLISHED

measured in humans, with a comparison group

PLAUSIBLE

supported by mechanism, animal studies or observation

HYPOTHESIS

a likely connection that still needs to be tested

Black Cumin (Nigella sativa) at a Glance

ORIGIN:

Black cumin (*Nigella sativa*) is an annual plant from the buttercup family. The seeds contain 30–40 % fixed oil, 0.5–1.5 % essential oils and secondary plant compounds such as thymoquinone, the main active constituent. Black cumin has traditionally been used as a spice and remedy in the Middle East, South Asia and North Africa. Modern research focuses primarily on seeds, oil extracts and isolated thymoquinone fractions; bioavailability and pharmacokinetics are only partially elucidated.

EVIDENCE BASE:

1,858 evaluated papers · 95 controlled human studies · 137 observational studies · 115 review articles · 426 animal studies · 331 cell-culture studies

STRONGEST EVIDENCE:

- **Inflammatory processes:** Meta-analysis (2023) of 20 RCTs with 1,086 participants shows significant reductions in CRP, TNFα and MDA together with increases in antioxidant enzymes (SOD, GPx, TAC) after at least four weeks of *Nigella sativa* supplementation. Heterogeneous doses and preparations limit generalisability.
- **Viral infections** Combination therapy of honey and *Nigella sativa* shortened symptom relief by approximately 50 % in COVID-19 patients (4 vs. 7 days) and reduced 30-day mortality (4 % vs. 18 %). The contribution of *Nigella sativa* alone was not examined.
- **Metabolism:** Systematic review (2019) of seven studies in type-2 diabetes shows significant reductions in fasting blood glucose, HbA1c and insulin resistance together with an increase in serum insulin. Marked variability in dose and preparation limits the strength of the findings.
- **Bone and joints** Study in 120 postmenopausal women (2022) provides a preclinical indication of reduced alkaline phosphatase (ALP) after six months of *Nigella sativa* oil (1,000 mg/day) combined with alendronate, calcium and vitamin D. Clinical endpoints such as fracture rates were not investigated.
- **Safety** Phase-I study (2022) in 70 healthy volunteers examined the safety of thymoquinone-rich *Nigella sativa* oil (200 mg/day for 90 days). No significant changes in haematological or biochemical parameters; lipid profile improved within the reference range.

LIMITATIONS:

- Controlled human studies on *Nigella sativa* are methodologically heterogeneous and frequently conducted with small samples or short durations. Standardisation of extracts (e.g. thymoquinone content) and dosage forms varies widely, complicating reproducibility and comparability.
- Lack of blinding or placebo controls in some studies as well as unclear long-term effects and clinical endpoints (e.g. morbidity, mortality) restrict the robustness of the data.
- The effect of *Nigella sativa* alone has not been isolated in many studies (e.g. combinations with honey, vitamin D or other substances), so the contribution of individual components remains unclear.

CLASSIFICATION:

Controlled human studies on black cumin (*Nigella sativa*) indicate anti-inflammatory, antioxidant and metabolic effects. The clinical relevance of these findings remains to be clarified because of methodological heterogeneity and the absence of long-term data.

1. What Black Cumin Is and How It Is Studied

Black cumin (*Nigella sativa*) is an annual plant from the buttercup family. The seeds contain **fixed oil** (30–40 %), **essential oils** (0.5–1.5 %) and **secondary plant compounds** such as **thymoquinone**, which is discussed as the principal active constituent. Modern research examines primarily **seeds**, **oil extracts** and isolated **thymoquinone fractions**.

Bioavailability and **pharmacokinetics** of black-cumin constituents are only partially elucidated. Studies employ different **extraction methods** (cold-pressed, ethanolic, aqueous) and **standardisations** (e.g. to thymoquinone content). This hampers comparisons between papers. In addition, **dosage forms** (capsules, oil, powder) and **routes of administration** (oral, topical, inhalational) vary. The majority of human studies use **oil extracts**, whereas preclinical work often employs **isolated thymoquinone compounds**.

2. What the Studies Show in Detail

The key human studies and the most important reviews — by therapeutic area, with population, duration, preparation, outcome measure and result as reported in the original papers. Numbers appear only where the work states them.

Distribution of **controlled human studies** by therapeutic area — the figures are not additive because one paper may be assigned to several areas:

Therapeutic Area	Controlled Studies
Inflammatory processes	42
Safety and tolerability	33
Metabolism	30
Immune system	21
Oxidative stress	20

Therapeutic Area	Controlled Studies
Fatigue and stress	18
Viral infections	12
Oncology	10

Inflammatory Processes

The meta-analysis of 20 randomised controlled trials (RCTs) with a total of 1,086 participants (2023) examined the effect of **Nigella sativa** supplements on inflammatory and oxidative-stress markers. Participants received **Nigella sativa** preparations in varying doses (not uniformly specified in the abstract) for at least four weeks (duration varied by study). Measured were serum levels of C-reactive protein (CRP), tumour necrosis factor α (TNFα), malondialdehyde (MDA), total antioxidant capacity (TAC), glutathione peroxidase (GPx) and superoxide dismutase (SOD). The results showed significant reductions in CRP (Standardised Mean Difference [SMD] = -2.28; 95 % CI: -3.20, -1.37; p < 0.001), TNFα (SMD = -1.21; 95 % CI: -2.15, -0.26; p = 0.013) and MDA (SMD = -2.15; 95 % CI: -3.37, -0.93; p < 0.001). At the same time TAC (SMD = 2.28; 95 % CI: 1.29, 3.27; p < 0.001), GPx (SMD = 1.23; 95 % CI: 0.25, 2.22; p = 0.014) and SOD (SMD = 2.05; 95 % CI: 1.22, 2.88; p < 0.001) rose significantly. Interleukin-6 (IL-6) showed no significant change (SMD = -1.13; 95 % CI: -2.72, 0.46; p = 0.162). The heterogeneity of the studies with regard to dose, preparation and population must be noted as a limitation, which complicates generalisation. In addition, data on long-term effects and clinical endpoints such as morbidity or mortality are lacking ⁶.

A randomised, double-blind, placebo-controlled study in 46 diabetic haemodialysis patients (2022) examined the effect of **Nigella sativa** oil (2 g/day) over 12 weeks. Measured were superoxide dismutase (SOD), MDA, TAC, high-sensitivity CRP (hs-CRP), glycosylated haemoglobin (HbA1c), fasting blood glucose (FBS) and insulin (INS). Compared with baseline, SOD, TAC and INS rose significantly while MDA, hs-CRP, HbA1c and FBS declined significantly. The study demonstrates a clear improvement in oxidative and inflammatory parameters, yet it is limited to a specific population (diabetic haemodialysis patients) and does not permit inferences about other patient groups. Data on the clinical relevance of the biochemical changes are also lacking ¹¹.

In a randomised, double-blind study with 100 patients with mild to moderate chronic obstructive pulmonary disease (COPD) (2020) the effect of **Nigella sativa** oil as add-on therapy was investigated. The intervention group received **Nigella sativa** oil in addition to standard medication, while the control group received only standard medication. After 3 months the **Nigella sativa** group showed a significant reduction in oxidative and inflammatory markers (thiobarbituric acid-reactive substances [TBARS], protein carbonyl [PC], IL-6, TNFα) as well as an increase in antioxidant parameters (SOD, catalase [CAT], reduced glutathione [GSH], GPx, vitamin C and E). Lung-function parameters also improved significantly. The study suggests a potential adjunctive effect of **Nigella sativa** in COPD, yet it is limited by the lack of exact dosage information and the short observation period of 3 months. Long-term data and a larger sample would be required to confirm the results ¹².

HYPOTHESIS The available preclinical studies suggest that **Nigella sativa** and in particular its main active constituent thymoquinone possess anti-inflammatory and antioxidant effects in animal and cell-culture models that are mediated via various signalling pathways. The consistent reduction of CRP, TNFα and MDA together with the increase in antioxidant enzymes such as SOD and GPx point to a possible mechanism of action that may be attributable to modulation of NF-κB, MAPK and other inflammation-relevant signalling pathways. However, studies that directly examine these molecular mechanisms in humans are still lacking, and clinical endpoints such as reduction of disease exacerbations or improvement in quality of life have not been tested.

Viral Infections

The participants were divided into four groups: moderate cases with honey/**Nigella sativa** (n = 107), moderate cases with placebo (n = 103), severe cases with honey/**Nigella sativa** (n = 50) and severe cases with placebo (n = 53). The combination therapy resulted in an approximately 50 % shorter time to symptom relief compared with placebo. Time to viral clearance was also shortened. 30-day mortality was significantly lower in the intervention group. A limitation is the lack of blinding of the honey component, which may have influenced the results. Because this was a combination study it remains unclear what proportion of the observed effects was attributable to **Nigella sativa** ⁴.

The participants were divided into four groups: **Nigella sativa** alone, vitamin D3 alone, combination of **Nigella sativa** and vitamin D3, and placebo. The combination therapy led to a significantly higher rate of viral clearance (negative PCR test) after 14 days compared with placebo (80 % vs. 20 %, p < 0.001). Symptom relief also occurred faster in the combination group than in the other groups. The study indicates a potential benefit of the combination of **Nigella sativa** and vitamin D3, yet it is limited by the open design and the short observation period. Because the group sizes were too small for an isolated evaluation of **Nigella sativa**, no conclusions can be drawn about the effect of the single substance.

HYPOTHESIS The antiviral and immunomodulatory properties of **Nigella sativa** may be attributable to inhibition of viral replication, modulation of cytokines (e.g. reduction of IL-6 and TNFα) and strengthening of antioxidant defence. The available studies on combinations of **Nigella sativa** with other substances such as honey or vitamin D3 suggest a possible benefit as adjunctive therapy in viral infections. However, studies that investigate the effect of **Nigella sativa** alone in larger populations and over longer periods are still lacking, so conclusions about the single substance cannot yet be drawn.

Bones and Joints

A randomised, controlled study with 90 older patients with knee osteoarthritis (2019) examined the effect of aromatherapy massages with a mixture of **Nigella sativa** oil, ginger and rosemary oil over 3 weeks (twice weekly 15–20 minutes). The results showed a significant improvement in pain and functional limitations (measured with the Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC]) as well as quality of life (measured with the OsteoArthritis Knee and Hip Quality of Life Scale [OAKHQoL]) in the aromatherapy group compared with the massage group and the placebo group after 4 weeks (p < 0.001). These effects persisted in the aromatherapy group after 8 weeks, whereas they were no longer detectable in the massage group. The study provides an indication of a potential pain-relieving and function-improving effect of the combination, yet it does not permit conclusions about the effect of **Nigella sativa** oil alone.

A randomised, triple-blind, placebo-controlled study with 120 postmenopausal women with osteoporosis or osteopenia (2022) investigated **Nigella sativa** oil (1000 mg/day) and nanomicellar curcumin individually and in combination over 6 months. The women also received alendronate (70 mg/week), calcium (500 mg/day) and vitamin D (400 IU/day). Serum levels of alkaline phosphatase (ALP), osteocalcin (OC) and osteopontin (OP) were measured. After adjustment for covariates the effect on ALP remained significant only in the combination group ($p = 0.004$). OC and OP levels showed no significant changes. The study suggests a potential benefit of the combination, yet it does not allow conclusions about the effect of the individual components. Clinical endpoints such as fracture rates were not investigated ¹³.

A further randomised, triple-blind study with 120 postmenopausal women (2021) investigated **Nigella sativa** oil (1000 mg/day) and nanomicellar curcumin individually and in combination with regard to the expression of microRNAs (miRNA-21, miRNA-422a, miRNA-503) over 6 months. Expression of miRNA-21 changed significantly, whereas miRNA-422a and miRNA-503 remained unchanged. The study provides an indication that the treatments investigated may influence the expression of bone-relevant microRNAs. Whether this results in changes in clinical endpoints remains to be clarified. It also remains unclear what proportion of the observed change was attributable to **Nigella sativa** oil, curcumin or secondary mechanisms ¹⁵.

HYPOTHESIS Preclinical studies and initial clinical indications suggest that **Nigella sativa** may have potentially positive effects on bone-metabolism parameters, particularly through modulation of inflammatory processes and oxidative stress. The observed changes in bone markers such as ALP and miRNA-21 in studies could point to inhibition of bone resorption or promotion of bone formation. However, studies that directly link these effects with clinical endpoints such as fracture rates or pain reduction in humans are still lacking, and preclinical findings cannot be transferred to humans.

Metabolism

A randomised, double-blind, placebo-controlled study with 43 patients with type-2 diabetes (2021) investigated the effect of **Nigella sativa** oil extract (2×500 mg/day) over 8 weeks. The study suggests a potential metabolic effect of **Nigella sativa**, yet it is limited by the small sample and the short observation period. Data on long-term effects and effects in other populations are also lacking ³.

A systematic review (2019) analysed seven studies on the effect of **Nigella sativa** on surrogate parameters in type-2 diabetes. The results showed a significant reduction in fasting blood glucose, postprandial blood glucose, HbA1c and insulin resistance as well as an increase in serum insulin. The studies nevertheless varied considerably with regard to dosage, preparation and duration, which makes generalisation difficult. The review examined only surrogate parameters; clinical endpoints such as diabetic complications or mortality were not investigated and do not permit conclusions about a clinical effect ²⁵.

A phase-I study with 70 healthy volunteers (2022) investigated the safety of thymoquinone-rich **Nigella sativa** oil (BlaQmax®, 200 mg/day) over 90 days. The results showed no significant changes in haematological or biochemical parameters (liver enzymes, renal function). Only the lipid profile improved significantly (reduction of total cholesterol, LDL, VLDL and triglycerides, $p < 0.05$), yet remained within the normal range. The study confirms the safety of **Nigella sativa** oil at the investigated dosage, yet it does not permit conclusions about efficacy in metabolic diseases ⁵.

HYPOTHESIS Some of the controlled human studies suggest that **Nigella sativa** may have potentially positive effects on glucose and lipid metabolism as well as on cardiovascular risk factors such as blood pressure and body weight. The observed effects could be attributable to the antioxidant and anti-inflammatory properties of thymoquinone, which reduce insulin resistance and lipid peroxidation. However, long-term studies that link these effects with clinical endpoints such as reduction of diabetic complications or cardiovascular events are still lacking.

Skin

A randomised, double-blind, placebo-controlled study with 62 breast-cancer patients (2019) investigated the effect of **Nigella sativa** gel (5 %) on the prevention of acute radiodermatitis. The patients applied the gel or placebo twice daily during radiotherapy. The results showed a significantly lower incidence of radiodermatitis in the **Nigella sativa** group compared with placebo ($p < 0.05$ for all weeks except week 2, $p = 0.36$). Onset of grade 2 and 3 RTOG/EORTC toxicity was also delayed (35 vs. 29 days, $p = 0.00$; 42 vs. 40 days, $p = 0.01$) as well as onset of moist desquamation (37 vs. 33 days, $p = 0.01$). Pain was significantly higher in the placebo group than in the **Nigella sativa** group. The study provides an indication of a possible protective effect of **Nigella sativa** in radiodermatitis, yet it is limited by the small sample and the lack of investigation of long-term effects ⁷.

An observational study with 152 patients with allergic diseases (2003) investigated the effect of **Nigella sativa** oil (40–80 mg/kg/day) over an unspecified period. The results showed a subjective improvement in symptoms (nasal dryness, itching, crusting) in allergic rhinitis, bronchial asthma and atopic eczema. Laboratory parameters such as IgE and eosinophil count showed no significant changes. The study suggests a potential symptomatic relief by **Nigella sativa**, yet it is limited by the absence of a control group and the subjective assessment of symptoms ²⁴.

HYPOTHESIS The available controlled and observational studies suggest that **Nigella sativa** may have potentially protective and symptomatic effects in skin and mucosal disorders, particularly through its antioxidant, anti-inflammatory and immunomodulatory properties. The observed effects could be attributable to inhibition of inflammatory mediators and promotion of skin-barrier function. However, controlled studies that investigate these effects in larger populations and over longer periods are still lacking.

Oncology

Reviews and preclinical studies (2013–2021) summarise the potential anticarcinogenic properties of thymoquinone, the main active constituent of **Nigella sativa**. In preclinical models (in vitro and in vivo) thymoquinone showed antiproliferative, pro-apoptotic, anti-angiogenic and immunomodulatory effects in various tumour cell lines (e.g. glioblastoma, breast cancer, prostate cancer). The mechanisms of action include modulation of apoptosis signalling pathways (e.g. activation of p53, inhibition of NF- κ B), induction of cell-cycle arrest and inhibition of metastasis. Chemosensitisation of tumour cells to conventional chemotherapeutic agents was also observed. These findings are nevertheless based on preclinical models, and investigation of these effects in humans remains to be done. Bioavailability and pharmacokinetics of thymoquinone are also limited, which complicates clinical application ^{21 23 26}.

HYPOTHESIS The preclinical data suggest that thymoquinone could be a promising candidate for the development of new oncological therapies, particularly because of its ability to modulate multiple signalling pathways and overcome chemoresistance. However, further studies are necessary to improve bioavailability, evaluate toxicity and confirm efficacy in clinical trials.

Oxidative Stress

A randomised, single-blind, controlled crossover study with 30 children with therapy-resistant epilepsy (2013) investigated the effect of **Nigella sativa** oil as add-on therapy to antiepileptic drugs over 4 weeks. The results showed no significant differences between the **Nigella sativa** group and placebo with regard to seizure frequency or seizure severity. Oxidative-stress markers (TAC, MDA) likewise showed no significant changes. However, 8 patients experienced a more than 50 % reduction in seizure frequency/severity after **Nigella sativa** administration. Data on long-term effects and on the clinical relevance of the observed effects are also lacking ¹⁰.

An observational study (2017) summarises the antioxidant and pro-oxidant properties of thymoquinone. Thymoquinone showed a selective antioxidant effect in healthy cells and a pro-oxidant effect in tumour cells in vitro, which led preclinically to inhibition of tumour growth. The study points to a dual mode of action of thymoquinone, but is limited by the absence of clinical data. It also remains unclear whether these effects are reproducible in preclinical models and whether they play a role in humans ²².

HYPOTHESIS The antioxidant properties of **Nigella sativa** and thymoquinone could play a central role in the modulation of oxidative stress and inflammatory processes. The available data suggest that thymoquinone is able to neutralise reactive oxygen species (ROS) in healthy cells, while acting pro-oxidatively in tumour cells or under pathological conditions. However, clinical studies that directly investigate these effects in humans and link them to clinical endpoints are still lacking.

Overall Picture

The available studies provide consistent indications of the anti-inflammatory, antioxidant and immunomodulatory properties of **Nigella sativa** and its main active constituent thymoquinone. These effects were observed in various populations (e.g. patients with diabetes, COPD, viral infections, osteoporosis) and over different periods (4 weeks to 6 months). Several controlled studies showed a reduction in inflammatory markers such as CRP and TNFα as well as an increase in antioxidant enzymes such as SOD and GPx. In addition, studies provide indications of potential metabolic effects, particularly on the improvement of glucose and lipid metabolism as well as on cardiovascular risk factors.

Despite these promising results, research is still outstanding in some areas. In particular, clinical studies in oncology that confirm the preclinically observed anticarcinogenic effects of thymoquinone in humans are lacking. Controlled studies with larger samples and longer observation periods are also required in the fields of bone and joint health as well as skin diseases. In addition, the studies vary considerably with regard to dosage, preparation and population, which makes generalisation of the results difficult. Systematic long-term studies with clinical endpoints are necessary to evaluate the therapeutic relevance of **Nigella sativa** conclusively.

Methodology of the Evidence Base

The available studies encompass a broad spectrum of designs, including randomised controlled trials (RCTs), observational studies and reviews. The duration of the interventions varied between 2 weeks and 6 months, with most studies covering a period of 4 to 12 weeks. Typical endpoints were biochemical markers (e.g. CRP, TNFα, HbA1c, lipid profile), clinical parameters (e.g. symptom relief, pain reduction), virological parameters (e.g. virus clearance), functional tests (e.g. lung function parameters) and structural measurements (e.g. bone density measurement). Systematic weaknesses of the studies are the frequently missing standardisation of the

NIGELLA SATIVA

preparations (e.g. oil, extract, powder) and dosages, which makes direct comparisons difficult. In addition, long-term data on safety and efficacy as well as studies with clinical endpoints such as morbidity, mortality or quality of life are often lacking. Many studies are limited to specific populations (e.g. diabetic haemodialysis patients, postmenopausal women), so transferability to other patient groups remains unclear. Another deficit is the absence of dose-response studies that determine the optimal dosage for different indications.

Thymoquinone as a Panacea? The Discrepancy Between Laboratory and Clinic

THYMOQUINONE

, the most frequently studied constituent of black seed, shows diverse effects in **cell cultures** and **animal models**: **antiproliferative**, **anti-inflammatory**, **antioxidant** and **immunomodulatory**. These findings often lead to the assumption that black seed extracts exert similar effects in humans. However, **transferability** is questionable. Preclinical models often use **high concentrations** in the investigated dose ranges or **direct applications** (e.g. injections), which do not correspond to oral intake. In addition, **pharmacokinetic data** on the bioavailability of thymoquinone in humans are lacking.

The

CONTROLLED HUMAN STUDIES

do not provide a **uniform picture**. While some studies report **improvements in inflammatory markers** or **metabolic parameters**, others show **no significant effects**. Even in similar areas of application (e.g. diabetes), the results vary considerably. One reason for this is the **lack of standardisation** of the extracts. Studies use different **manufacturing processes**, **dosages** in the investigated ranges and **formulations**, which makes direct comparisons impossible. In addition, many studies are **not blinded** or have **no placebo control**, which further limits the strength of the evidence.

3. How Robust the Research Is

Research on **black seed** is distributed across **basic research**, **animal models** and **cell cultures**. In humans, **observational studies** and **controlled studies** are available. The controlled human studies primarily investigate **inflammatory processes**, **metabolic parameters** and **safety**. Further focal points are **antioxidant effects**, **immunomodulation** and **antiviral approaches**. Oncological and musculoskeletal applications are less frequently represented, but are

investigated in preclinical studies.

The **robustness** of the data is limited. Many human studies have **small samples** and **short durations**. The **standardisation** of the extracts is inconsistent, which complicates reproducibility. Reviews emphasise **molecular mechanisms** (e.g. NF-κB inhibition, antioxidant enzyme activation in preclinical models), yet the **transfer into clinical effects in humans** is still outstanding. Some controlled studies show **heterogeneous results** – even for similar questions. Methodological shortcomings such as missing **blinding** or **placebo controls** are common in older studies.

4. What Is Frequently Claimed — and What the Data Support

CLAIM	EVIDENCE BASE
Black seed in cancer	Preclinical data indicate antiproliferative effects of thymoquinone. Controlled human studies are lacking. Observational studies are not meaningful.
Antiviral effect (e.g. in COVID-19)	Individual controlled studies examine combination therapies. There are no robust data on monotherapies or long-term effects.
Use in autoimmune diseases	Animal models demonstrate immunomodulatory effects. Human studies are still emerging and methodologically weak. No recommendation can be derived.
Topical application (e.g. in skin diseases)	Individual studies on wound healing or radiation dermatitis. The data situation is still developing, with no standardised protocols.

5. The Most Robust Studies

Ordered by strength of evidence, not by familiarity. The complete evaluation comprises considerably more studies; the most robust ones are presented here.

Controlled Human Studies

- 1 Review on Clinical Trials of Black Seed (Nigella sativa) and Its Active Constituent, Thymoquinone (2017)
- 2 Prophetic Medicine-Nigella Sativa (Black cumin seeds) - Potential herb for COVID-19? (2020)
- Effects of aromatherapy massage on pain, functional state, and quality of life in an elderly individual with knee osteoarthritis (2019)
- 3 Effect of Nigella sativa oil extract on cardiometabolic risk factors in type 2 diabetes: A randomized, double-blind, placebo-controlled clinical trial (2021)
- 4 Honey and Nigella sativa against COVID-19 in Pakistan (HNS-COVID-PK): A multicenter placebo-controlled randomized clinical trial (2023)
- 5 A phase I clinical trial to evaluate the safety of thymoquinone-rich black cumin oil (BlaQmax®) on healthy subjects: Randomized, double-blinded, place (2022)
- 6 The effect of Nigella sativa (black seed) on biomarkers of inflammation and oxidative stress: an updated systematic review and meta-analysis of random (2023)
- 7 Nigella sativa L. for prevention of acute radiation dermatitis in breast cancer: A randomized, double-blind, placebo-controlled, clinical trial (2019)
- A new nutraceutical (Livogen Plus®) improves liver steatosis in adults with non-alcoholic fatty liver disease (2022)
- 8 Effects of Nigella sativa seeds (black cumin) on insulin secretion and lipid profile: A pilot study in healthy volunteers (2019)
- 9 Nigella Sativa (Black Seeds), A Potential Herb for the Pharmacotherapeutic Management of Hypertension - A Review (2021)
- 10 The clinical outcome of adjuvant therapy with black seed oil on intractable paediatric seizures: a pilot study (2013)
- 11 Effect of Nigella Sativa Oil on Oxidative Stress, Inflammatory, and Glycemic Control Indices in Diabetic Hemodialysis Patients: A Randomized Double-BI (2022)
- 12 Therapeutic effects of black seed oil supplementation on chronic obstructive pulmonary disease patients: A randomized controlled double blind clinical (2020)
- 13 Efficacy of nanomicelle curcumin, <i>Nigella sativa</i> oil, and their combination on bone turnover markers and their safety in postmenopausal women w (2022)
- 14 Topical Nigella Sativa for nasal symptoms in elderly (2014)
- The effect of <i>Nigella sativa</i> and vitamin D3 supplementation on the clinical outcome in COVID-19 patients: A randomized controlled clini (2022)
- 15 The effect of nanomicelle curcumin supplementation and Nigella sativa oil on the expression level of miRNA-21, miRNA-422a, and miRNA-503 gene in postm (2021)

- ¹⁶ Effect of Nigella sativa supplementation on kidney function, glycemic control, oxidative stress, inflammation, quality of life, and depression in diabetics (2022)
- ¹⁷ Does Nigella sativa supplementation improve cardiovascular disease risk factors? A comprehensive GRADE-assessed systematic review and dose-response meta-analysis (2025)
- ¹⁸ The Therapeutic Effects of Nigella sativa on Skin Disease: A Systematic Review and Meta-Analysis of Randomized Controlled Trials (2022)
- ¹⁹ The effect of Nigella sativa on TAC and MDA in obese and overweight women: secondary analysis of a crossover, double blind, randomized clinical trial (2022)
- Chinese herbal medicine for the treatment of small intestinal bacterial overgrowth (SIBO): A protocol for systematic review and meta-analysis (2020)
- ²⁰ Effect of an orally formulated processed black cumin, from Iranian traditional medicine pharmacopoeia, in relieving symptoms of knee osteoarthritis: A randomized controlled trial (2017)

6. Summary

The available human studies demonstrate primarily effects of Nigella sativa on inflammation and oxidative stress markers, in particular through reductions in CRP, TNF α and MDA as well as increases in antioxidant enzymes (SOD, GPx, TAC). They also provide indications of positive metabolic effects (e.g. lowering of blood glucose, HbA1c and lipids). Preclinical studies suggest antiviral and immunomodulatory effects, especially in combination with other substances, although these effects have not been investigated in humans. The safety of Nigella sativa extracts in defined doses is confirmed in short-term studies, with no serious adverse effects reported. However, data on clinical endpoints such as morbidity, mortality or long-term effects remain insufficient.

HYPOTHESIS The consistent effects on inflammation and oxidative stress markers point to systemic mechanisms of action that may be mediated via modulation of signalling pathways such as NF- κ B, MAPK or antioxidant enzyme systems. Thymoquinone as the principal active compound could play a central role by inhibiting lipid peroxidation and improving insulin resistance in preclinical studies, although these effects have not been confirmed in humans. The observed antiviral effects may be attributable to preclinical indications of inhibition of viral replication and modulation of cytokines (e.g. IL-6, TNF α), although clinical evidence is lacking. In the area of bone and joints the effects may indicate preclinical findings on the inhibition of inflammatory processes and the modulation of bone-relevant microRNAs (e.g. miRNA-21), although direct evidence in humans is absent. In addition, studies linking biochemical changes to clinical endpoints are still required.

Large-scale, long-term and methodologically robust studies would be needed to clarify the clinical relevance of Nigella sativa. These should employ standardised extracts (e.g. standardised for thymoquinone content), incorporate clear clinical endpoints (e.g. reduction in disease flares, improvement in quality of life, fracture rates) and investigate the effect of Nigella sativa alone. In addition, molecular mechanisms (e.g. NF- κ B inhibition, microRNA modulation) would need to be validated directly in humans to assess the transferability of preclinical findings. Studies on long-term effects, interactions with standard therapies and optimal dosing for specific indications would be particularly relevant.

7. Broader Context

PLAUSIBLE Black cumin and its constituents, particularly thymoquinone, stand in a plausible connection with the molecular chains of inflammation resolution and antioxidant defence. Preclinical data show that thymoquinone inhibits the activity of the transcription factor NF- κ B, which plays a central role in the regulation of pro-inflammatory cytokines such as IL-6 and TNF. In addition, the expression of antioxidant enzymes such as superoxide dismutase (SOD) and glutathione peroxidase is promoted via the Nrf2 signalling pathway. These mechanisms indicate that black cumin not only exerts anti-inflammatory effects but potentially also supports the active termination of inflammatory processes (resolution). Preclinical models provide indications, for example through reduced CRP and IL-6 levels in inflammatory diseases, although transferability to humans remains to be clarified. The heterogeneity of extraction methods and dosages also complicates the assessment of actual efficacy.

PLAUSIBLE Controlled human studies show that black cumin extracts have measurable effects on inflammatory markers and metabolic parameters, albeit with considerable limitations. In studies on metabolic diseases such as type 2 diabetes or obesity, significant reductions in CRP, IL-6 and TNF were observed after several weeks of intake of standardised oil extracts. These changes correlate in part with improved metabolic parameters such as fasting blood glucose or HbA1c values. In inflammatory skin diseases such as psoriasis or atopic dermatitis, local and systemic inflammatory markers were also reduced in placebo-controlled studies. Nevertheless, the results are inconsistent: some studies report no significant effects, which can be attributed to differences in dosage, extraction procedures or study populations. In addition, long-term data on safety and efficacy are lacking, particularly with chronic use. The methodological quality of many studies is limited, as blinding and placebo controls are often inadequately implemented.

HYPOTHESIS From the existing data it can be hypothesised that black cumin extracts – particularly standardised thymoquinone fractions – could play a role in the modulation of chronic inflammatory and metabolic processes, provided that bioavailability and pharmacokinetics are optimised. Since preclinical and clinical indications of an influence on inflammation resolution and antioxidant defence are available, it would be worth examining whether black cumin in combination with other resolution mediators (e.g. lipoxins or protectins) unfolds synergistic effects. In addition, it should be investigated whether the observed effects on inflammatory markers actually lead to a clinically relevant improvement in disease courses, for example in autoimmune diseases or chronic inflammatory bowel diseases. Critically to be clarified are the optimal extraction and standardisation procedures to ensure reproducible results. In the long term, multicentre, blinded studies with clearly defined endpoints would be necessary to validate the therapeutic benefit of black cumin components. Particularly relevant appears the question of whether thymoquinone could serve as a lead structure for the development of new active substances that specifically intervene in the resolution of inflammation.

8. What Remains Open

- **Bioavailability:** How well is thymoquinone absorbed and metabolised after oral administration?
- **Long-term Safety:** Data on chronic use are lacking, particularly in the investigated dose ranges.
- **Combination Therapies:** Are there synergistic effects with conventional medications (e.g. in oncology)?

9. Further Paths

Topics, pathways and chains in which this substance occurs — for all those who want to look beyond the substance.

- Ending Inflammation Instead of Suppressing It: Resolution and Natural Substances
- Oxidative Stress, Mitochondria and Energy

Frequently Asked Questions

Can black cumin oil be used in diabetes?

Some controlled studies investigate **black cumin oil** in **type 2 diabetes**. **Metabolic parameters** such as **fasting blood glucose** or **HbA1c** are measured. The results are **contradictory**: Some works report **improvements**, others show **no effects**. The studies differ in the investigated **dosage ranges**, **duration** and **extract standardisation**. An **empirical recommendation** is not possible due to the heterogeneous data situation.

Are there interactions with medications?

Preclinical data suggest **possible interactions**, particularly with **CYP450 enzymes** that influence the **metabolism** of medicinal products. In-vitro studies show **inhibition or induction** of these enzymes by **thymoquinone**. However, clinical data are lacking. Caution is advised with **concurrent use of immunosuppressants** or **anticoagulants**, as **black cumin extracts** may have **immunomodulatory** and **coagulation-influencing** effects.

How is the quality of black cumin extracts ensured?

The **quality** of black cumin extracts varies considerably. Important **quality characteristics** are the **thymoquinone content**, the **extraction method** (e.g. cold-pressed vs. solvent-based) and **contaminants** (e.g. heavy metals, pesticides). Some studies use **standardised extracts** (e.g. BlaQmax®), yet many works provide **no detailed specifications**. For practical use, **certified products** with **analytical documentation** are recommended.

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Research, put in context. Every statement leads to the original paper; the decision in the individual case rests with the treating professional.
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