

LETTER

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Nigella sativa supplementation to treat symptomatic mild COVID-19: A structured summary of a protocol for a randomised, controlled, clinical trial

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Abstract

Objectives: To investigate the potential efficacy of *Nigella sativa* (NS) oil supplementation on the outcomes of patients with mild Coronavirus Disease 2019 (COVID-19).

Trial design: Prospective, two-arm, parallel-group, randomised (1:1 allocation ratio), open-label, controlled, exploratory phase II clinical trial of oral NS oil in patients with mild COVID-19.

Participants: Inclusion Criteria:

- Patients with mild COVID19 (defined as upper respiratory tract infection symptoms in the absence of clinical or radiological signs of pneumonia).
- Adult (18 - 65 years old).
- Written informed consent by the patient (or legally authorized representative) prior to initiation of any study procedures.
- All patients should understand and agree to comply with planned study procedures.
- Polymerase chain reaction (PCR)-confirmed infection with Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) from throat swab.

Exclusion Criteria:

- Patients with pneumonia or severe illness requiring admission to intensive care unit.
- Severe chronic kidney disease (i.e. estimated glomerular filtration rate [eGFR] < 30 mL/min) or end stage renal disease requiring dialysis
- Severe chronic liver disease (Alanine transaminase [ALT] or Aspartate transaminase [AST] > 5 times the upper limit of normal).
- Pregnancy or breast feeding.
- Anticipated transfer within 72 hours to another hospital that is not a study site.
- Allergy to the study medication

(Continued on next page)

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(Continued from previous page)

The trial is currently conducted on patients recruited from King Abdulaziz University Hospital, Jeddah, Saudi Arabia.

Intervention and comparator: Intervention group: *Nigella sativa* oil (MARNYS® Cuminmar) 500 mg softgel capsules, one capsule orally twice daily for 10 days plus standard of care treatment (antipyretic, antitussive). Comparator group: standard of care treatment.

Main outcomes: Proportion of patients who clinically recovered (defined as 3 days of no symptoms) within 14 days after randomisation.

Randomisation: Patients will be randomly assigned to treatment or control groups in a 1:1 ratio using a computer-generated randomization scheme (Random permuted blocks of 10) developed using the web-based program: <http://www.randomization.com>.

Blinding (masking): No blinding.

Numbers to be randomised (sample size): Up to 200 eligible patients will be randomly assigned to either treatment or control groups.

Trial Status: Protocol version 1, as of July 14, 2020. Recruitment was started on May 21, 2020. The intended completion date is December 31, 2020.

Trial registration: ClinicalTrials.gov Identifier: [NCT04401202](https://clinicaltrials.gov/ct2/show/study/NCT04401202). Date of trial registration: May 26, 2020.

Full protocol: The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest of expediting dissemination of this material, the familiar formatting has been eliminated; this letter serves as a summary of the key elements of the full protocol.

Keywords: COVID-19, SARS-CoV-2, Randomised controlled trial, protocol, *Nigella sativa*, black seed, phytotherapy

Supplementary information

Supplementary information accompanies this paper at <https://doi.org/10.1186/s13063-020-04647-x>.

Additional file 1.

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Authors' contributions

AK, EK, TM initiated the study and concept development. AK, EK, AM, TM, MB, SW, HM contributed to the study design. EK, MB, AK supervised the project. AK obtained necessary approvals. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding

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Availability of data and materials

Only investigators will have access to the final trial dataset.

Ethics approval and consent to participate

The study was approved by the ethical committee of King Abdulaziz University Hospital (266-20) on May 14, 2020. We confirm that this trial has received ethical approval from the appropriate ethical committee described above. Each participant will be instructed to read an information note and to sign a consent form for participation.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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