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Trials

LETTER Open Access

Letter to the editor: Study Summary - Randomized Control Trial of Omega-3 Fatty Acid Supplementation for the Treatment of COVID-19 Related Olfactory Dysfunction

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Abstract

Objectives: To evaluate a therapeutic role for omega-3 fatty acid supplementation in the treatment of olfactory dysfunction associated with COVID-19 infection

Trial design: Randomized, double-blinded, placebo-controlled trial

Participants: Eligible patients are adults with self-reported new-onset olfactory dysfunction of any duration associated with laboratory-confirmed or clinically suspected COVID-19 patients. Exclusion criteria include patients with pre-existing olfactory dysfunction, history of chronic rhinosinusitis or history of sinus surgery, current use of nasal steroid sprays or omega-3 supplementation, fish allergy, or inability to provide informed consent for any reason. The trial is conducted at Mount Sinai Hospital

Intervention and comparator: The intervention group will receive 2000 mg daily of omega-3 supplementation in the form of two "Fish Oil, Ultra Omega-3" capsules (product of Pharmavite®) daily. The comparator group will take 2 placebo capsules of identical size, shape, and odor daily for 6 weeks.

Main outcomes: Each subject will take a Brief Smell Identification Test at study enrolment and completion after 6 weeks. The primary outcome will be change in Brief Smell Identification Test over the 6-week period.

Randomisation: Patients will be randomized by the Investigational Drug Pharmacy at the Icahn School of Medicine at Sinai via a computer-generated sequence in a 1:1 allocation to treatment or control arms.

Blinding (masking): Both participants and researchers will be blinded.

Numbers to be randomised (sample size): There will be 88 participants randomized to each group. A total of 176 participants will be randomized.

Trial Status: Protocol Version 1, 8/3/2020
Recruitment is ongoing, started 8/5/2020 with estimated completion 11/30/2020.

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Trial registration: The trial is registered on ClinicalTrials.gov with Protocol Identifier: NCT04495816.
Trial registration: ClinicalTrials.gov, NCT04495816. Registered 3 August 2020

Full protocol: The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1).

Keywords: COVID-19, Randomised controlled trial, protocol, olfactory dysfunction, omega-3 fatty acid, smell loss

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-020-04905-y.

Additional file 1. Full Study Protocol.

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Not applicable.

Authors' contributions

DL, AF, PF – study design, subject recruitment. KG, AA, KL, SN – subject recruitment, literature review. MS, PC, AS, SG – study design, subject recruitment. AI – study design, study oversight. The author(s) read and approved the final manuscript.

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Availability of data and materials

The final trial dataset will be accessible from the author on reasonable request. Contact David Lerner (e-mail david.lerner2@mountsinai.org).

Ethics approval and consent to participate

This study protocol was approved by the Institutional Review Board at the Icahn School of Medicine at Mount Sinai on 7/10/2020 (HS#:20-00511, GCO#20-1132 ISMMS).
Informed consent will be obtained from all participants. Only adults are included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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