

Covid-19 RCT: Honey and black cumin seed help speed up recovery in Covid-19 patients

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A randomised-controlled trial that is awaiting peer review suggests that Covid-19 patients who received a combination of honey and *Nigella sativa* recovered more quickly than those given a placebo.

Treatment with honey and *Nigella sativa* (also known as black cumin) was found to alleviate Covid-19 symptoms within six days, compared to 13 days in the control group.

In addition, subjects on the honey and *Nigella sativa* (HNS) treatment achieved a negative PCR test - used to diagnose Covid-19 - about four days earlier than subjects without the treatment.

According to the researchers, this is the first such trial studying a combination of HNS in Covid-19 patients.

The paper is published on the preprint server, medRxiv and has not yet been peer-reviewed yet.

Dr Sohaib Ashraf, who is the principal investigator of this study, and a research fellow at the Massachusetts General Hospital, Harvard Medical School, Boston, USA told *NutraIngredients-Asia*: "When COVID-19 struck in late March, soon it was clear to us that this disease is going to cause havoc across the globe and will act as a reset button for world economy.

So, we searched for clinical trials published regarding proven efficacy of any drug against COVID-19 but unfortunately, we identified no drug proven effective against COVID-19.

*"We searched on scientific literature for any miracle drug that can be globally accessible with wide range efficacy against viruses and other microbes along with anti-inflammatory, immune-modulatory, anti-coagulant properties and wide range of safety profile. In that search, we found honey and *Nigella sativa* were a perfect fit."*

Researchers said both honey and *Nigella sativa* show similar pharmacological profiles with its anti-viral, anti-microbial, anti-inflammatory effects especially in upper respiratory tract infections.

"We reasoned that the combination could be more effective in attenuating severity of the disease, controlling viral replication and curing COVID-19 patients," they wrote.



Study design

The trial was conducted between **May to July 2020** as an urgent study during the peak of the Covid-19 outbreak in Pakistan.

In total, 313 patients were enrolled in the RCT, and recruited from four medical care facilities in Lahore, Pakistan.

210 subjects were categorised as moderate cases, identified by cough, fever, sore throat, nasal congestion, and shortness of breath, while 103 subjects were severe cases, identified by fever, cough, pneumonia, and respiratory distress.

The subjects were **randomised** into the treatment or placebo group.

Nigella Sativa:

150# = 68 kg = 5.4 gm/day (~ 1 tsp)

200# = 91 kg = 7.3 gm/day ~ 1.5 tsp/day

In the treatment group, subjects were given **honey (1g/kg/day) and Nigella sativa (80mg/kg/day) for up to 13 days.**

These were given **two to three times a day depending on the patient's comfort. Honey was dissolved in 250mL of warm water, while Nigella sativa was provided in capsules.**

There are 64 calories in 1 tablespoon of raw bee honey.

Both honey and Nigella sativa were provided by Smile Welfare Organization, a non-profitable organisation based in Pakistan.

The control group received empty capsules.

Honey:

150# = 68 kg = 68 gm honey /day ~ 3 TBSP /day;

200# = 91 kg = 91 gm honey/day = 4.5 TBSP /day

In addition, all Covid-19 patients received standard care therapy as advised by the physician, comprising of anti-pyretic drugs, antibiotics, supplemental oxygen and mechanical ventilation if required.

Subjects were assessed for clinical symptoms daily for 13 days, and **underwent SARS-CoV-2 RT-PCR tests if found to remain asymptomatic for at least 48 hours.**

For patients who were discharged before day 13 or were home-quarantined, the follow-up was done by telemedicine.

The primary outcomes were viral clearance (negative PCR test) and alleviation of symptoms. Secondary outcome was 30-day mortality.

Findings

HNS was found to alleviate Covid-19 symptoms in four days and six days in moderate and severe cases respectively ($p < 0.0001$), compared to seven and 13 days in the control group.

Viral clearance also occurred **four days earlier** for the HNS group in both moderate and severe cases, compared to the control group.

HNS also reduced mortality among severe patients ($p = 0.029$).

In moderate cases, 96.26% of moderate cases patients managed to resume daily activities by day 10, compared to 68.93% in the control group.

In the severe cases, HNS cases were discharged by day 10 while control cases were observed to still be hospitalised requiring oxygen therapy.

30-day mortality was reported as 18.87% in control group and 4% in the HNS treatment group.

These results show that HNS promotes viral clearance, reduces severity of the disease and mortality, and is a safe and effective therapy for moderate to severe Covid-19 cases, say researchers.

Ashraf explained this combination treatment was affordable (<US\$5 for the whole treatment course), easily available over the counter, and easy to administer as a home-based remedy.

"We have seen the patients getting miraculously getting better with this treatment regimen even outside the trial. So, we are sure this is the only hope that the humanity has to fight against this widespread disease.

As an inexpensive nutraceutical, this could be used alone or in combination with other drugs for additive effects. The treatment is very likely to reduce burden on health care systems in a significant manner.

"It has a great potential for commercialisation but in order to prove whether it is the most effective treatment option available in the world, we may need to conduct larger RCTs."

One limitation of this study was its open label design.

Despite its randomised blinded design, Ashraf said only care providers, outcome assessors and data analysts were blinded. *"The patients were also blinded for Nigella sativa seeds but they knew the sweet thing that they were drinking was honey."*

In addition, **patients on ventilator support were not enrolled in this study.**

Researchers said a multinational study with a larger sample size is required to investigate potential variations in responses to the treatment in COVID-19 patients from different racial and ethnic origins.

Ashraf told us: *"We are planning to conduct a larger multi-national trial on this treatment modality and planning to keep patients on ventilator support included in study."*

Ashraf added the team was working on several ongoing clinical projects including an RCT for honey and black cumin seeds among health care workers to study the prophylactic potential of HNS. It is currently searching for funding.

Source: medRxiv

<https://doi.org/10.1101/2020.10.30.20217364>

"Efficacy of honey and Nigella sativa against COVID-19: HNS-COVID-PK Trial"

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