Comments (29)

Honey and *Nigella sativa* against COVID-19 in Pakistan (HNS-COVID-PK): A multi-center placebo-controlled randomized clinical trial

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SUMMARY

BACKGROUND No definitive treatment exists for Coronavirus Disease 2019 (COVID-19). Honey and *Nigella sativa* (HNS) have established antiviral, antibacterial, anti-inflammatory and immunomodulatory properties. Hence, we investigated efficacy of HNS against COVID-19. wide

METHODS We conducted a multicenter, placebo-controlled, randomized clinical trial at 4 centers in Pakistan. RT-PCR confirmed COVID-19 adults showing moderate or severe disease were enrolled in the study. Patients presenting with multi-organ failure, ventilator support, and chronic diseases (except diabetes mellitus and hypertension) were excluded. Patients were randomly assigned in 1:1 ratio to receive either honey (1 gm/Kg/day) and *Nigella sativa* seeds (80 mg/Kg/day) or placebo up-to 13 days along with standard care. The outcomes included symptom alleviation, viral clearance, and a 30-day mortality in intention-to-treat population. This trial was registered with ClinicalTrials.gov, **NCT04347382**.

RESULTS Three hundred and thirteen patients - 210 moderate and 103 severe - underwent randomization from April 30 to July 29, 2020. Among these, 107 were assigned to HNS whereas 103 to placebo for moderate cases. For severe cases, 50 were given HNS and 53 were given placebos. HNS resulted in ~50% reduction in time taken to alleviate symptoms as compared to placebo (Moderate (4 versus 7 days), Hazard Ratio [HR]: 6.11; 95% Confidence Interval [CI]: 4.23-8.84, P<0.0001 and severe (6 versus 13 days) HR: 4.04; 95% CI, 2.46-6.64, P<0.0001). HNS also cleared the virus 4 days earlier than placebo group in moderate (6 versus 10 days, HR: 5.53; 95% CI: 3.76-8.14, P<0.0001) and severe cases (8.5 versus 12 days, HR: 4.32; 95% CI: 2.62-7.13, P<0.0001). HNS further led to a better clinical score on day 6 with normal activity resumption in 63.6% versus 10.9% among moderate cases (OR: 0.07; 95% CI: 0.03-0.13, P<0.0001) and hospital discharge in 50% versus 2.8% in severe cases (OR: 0.03; 95% CI: 0.01-0.09, P<0.0001). In severe cases, mortality rate was four-fold lower in HNS group than placebo (4% versus 18.87%, OR: 0.18; 95% CI: 0.02-0.92, P=0.029). No HNS-related adverse effects were observed.
CONCLUSION HNS significantly improved symptoms, viral clearance and mortality in COVID-19 patients. Thus, HNS represents an affordable over the counter therapy and can either be used alone or in combination with other treatments to achieve potentiating effects against COVID-19.