MICROBIOME MODIFICATION AND IMPROVEMENT OF SIGNS AND SYMPTOMS OF COVID-19: ILEOCOLONIC-RELEASE NICOTINAMIDE IN A PROSPECTIVE, DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL

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A randomized controlled trial of oral nicotinamide in 900 unvaccinated outpatients with early COVID-19 found improved recovery from reduced physical performance at 2 weeks, alongside stabilization of gut microbiome changes.

KEY POINTS

- In the primary analysis population of symptomatic patients with at least one risk factor for severe COVID-19, 57.6% receiving nicotinamide (1,000 mg/d for 4 weeks) recovered from performance drop at week 2 versus 42.6% receiving placebo (absolute difference 15.0 percentage points, OR 1.33, 95% CI 1.03–1.70, P=0.004).
- Nicotinamide was superior to placebo for secondary endpoints including ability to perform normal activities (P=0.009) and shortness of breath (P=0.012).
- Microbiome sequencing showed substantial effects counteracting COVID-19 related changes, with restoration of tryptophan biosynthesis and activation of NAD salvage pathways in nicotinamide-treated patients.
- No relevant safety signals were observed in this trial of 867 participants who received the investigational ileocolonic-release nicotinamide formulation.
- The trial enrolled symptomatic, unvaccinated, non-hospitalized outpatients with PCR-proven early COVID-19 and may be most relevant to clinicians managing similar patient populations.

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