PREPARE-IT 2: The Prevention and Treatment of COVID-19 With EPA in Subjects at Risk - Intervention Trial

Purpose: To determine if icosapent ethyl (IPE) might be effective in reducing the risk of COVID-19 related morbidity or mortality in symptomatic non-hospitalized patients with a positive diagnosis of COVID-19.

Trial Design: Randomized, placebo-controlled trial of IPE vs placebo in adults ≥ 40y with a confirmed COVID-19 diagnosis and ≤ 7d of symptom onset. Dosing regimen consisted of 8g of IPE or matching placebo (4 capsules every 12h with food) for the first 3d followed by 4g of IPE or matching placebo (2 capsules every 12h with food) thereafter (day 4- day 28).

Primary Endpoints: COVID-19 related hospitalization (indication for hospitalization or hospitalization) or mortality up to 28 days.

Secondary Endpoints: COVID-19 hospitalizations or death.

Key Takeaways for the Clinician: IPE including the loading dose was well tolerated. Larger randomized trials with IPE are needed to establish whether IPE may have a role in the management of COVID-19 positive outpatients.

Results	IPE N= 986	Placebo N=1030	HR (95% CI)	P-value
Primary Outcome				
COVID-19 related hospitalization (indication for hospitalization or hospitalization) or death	110 (11.16%)	135 (13.69%)	0.84 (0.65;1.08)	0.166
Secondary Outcome				
COVID-19 hospitalization or death	53 (5.38%)	70 (6.80%)	0.78 (0.55;1.12)	0.18
Safety			**P-value**	
Any event, n (%)	164 (16.58%)	153 (14.85%)	0.30	
Conclusion: The lower rate of primary endpoint with IPE versus placebo was not statistically significant. IPE was well tolerated compared to placebo, though there was a slightly higher rate of discontinuation.				

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Results reflect the data available at the time of presentation.