Prevention and Treatment of COVID19 With EPA in Subjects at Risk – IntErvention Trial - PREPARE-IT 1

Contribution To Literature:

The PREPARE-IT 1 trial showed that use of high-dose IPE for 60 days did not prevent incident SARS-CoV-2 infection among healthy participants who did not have prior known infection with or vaccination against COVID-19.

Description:

The goal of the trial was to assess the safety and efficacy of icosapent ethyl (IPE) on reducing infection rate among participants at high-risk of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Study Design

Patients were randomized in a 1:1 open-label fashion to either IPE (4 g PO BID for 3 days, then 2 g BID for 60 days) (n = 850) or matching mineral oil placebo (n = 862).

- Total screened: 4,244
- Total number of enrollees: 1,712
- Duration of follow-up: 60 days
- Age: 40.5 years
- Percentage female: 55%

Inclusion criteria:

- ≥18 years
- Any participant who is exposed to the public

Exclusion criteria:

- Previous coronavirus disease 2019 (COVID-19) diagnosis
- Positive pregnancy test at the time of study entry
- Pregnancy or breastfeeding
- Received one or more doses of any SARS-CoV-2 vaccine or who has an appointment to receive the vaccine within 60 days

Other salient features/characteristics:

- Diabetes: 4%
- Bronchial asthma: 7%
- Hypercholesterolemia: 18%

Principal Findings:

The primary endpoint, SARS-CoV-2 positive at day 60, for IPE vs. placebo, was 7.9% vs. 7.1% (p = 0.58).

Secondary analyses for IPE vs. placebo:

- Change in high-sensitivity C-reactive protein (hsCRP) from baseline: 0 vs. 0
- Change in triglycerides from baseline: -2 vs. 7 mg/dl
- Change in InFLUenza Patient-Reported Outcome (FLU-PRO) score from baseline: 0.01 vs. 0.3
- Hospitalized for COVID-19: 0.1% vs. 0%

Interpretation:

The results of this trial indicate that use of high-dose IPE for 60 days did not prevent incident SARS-CoV-2 infection among healthy participants who did not have prior known infection with or vaccination against COVID-19. There was also no change in hsCRP in either arm, including in the placebo arm, which received mineral oil placebo. The higher dose of IPE (8 g/day) was well tolerated (REDUCE-IT trial used 4 g/day). PREPARE-IT 2 is examining the effect of IPE in SARS-CoV-2–positive nonhospitalized patients.

References:

Presented by Dr. Rafael Diaz at the European Society of Cardiology Virtual Congress, August 28, 2021.