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Title:
RANDOMIZED PHASE II TRIAL TO ASSESS SAFETY AND EFFICACY OF CAPRE IN MILD-TO-SEVERE HYPERTRIGLYCERIDEMIC PATIENTS

Objectives:
To evaluate the safety and efficacy of CaPre® to reduce fasting plasma TG (200-877 mg/dL) after 4 and 8 weeks versus Standard Of Care (SOC). Secondary endpoints were changes in TC, LDL-C, HDL-C, non-HDL-C, and HbA1c. Serum apolipoproteins (Apo-CIII, Apo-AI) were also assessed.

Background:
Long-chain polyunsaturated omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) have been shown to reduce hepatic secretion of TG-rich lipoproteins and plasma TG levels. CaPre® is a novel highly purified omega-3 krill oil extract with a high content of phospholipid-conjugated EPA and DHA.

Methods:
288 patients aged 18-75 from 34 centers were randomized in an open-label study to SOC, or CaPre given daily for 8 weeks with dose-doubling at week 4 for 0.5g, 1g, and 2g groups while 4g group was dosed for 8 weeks. Standard safety assessments were conducted. Statistical analysis was performed using ANOVA followed by post-hoc contrast analysis assessing % change between CaPre baseline, week 4 and 8 versus SOC.

Results:
CaPre SOC-adjusted 4-week TG % difference was -8% (p=NS), -16% (p=0.007), -13% (p=0.025) and -18% (p=0.002), for 0.5g, 1g, 2g, and 4g, respectively. The SOC-adjusted 8-week TG % difference was 2% (p=NS), -16% (p=0.021), -6% (p=NS) and -14% (p=0.038), for 0.5g, 1g, 2g, and 4g, respectively. CaPre 4g SOC-adjusted 8-week TC % difference was -7% (p=0.06) and non-HDL-C was -10% (p=0.036). Similarly to beneficial lipid effects, HbA1c was significantly lowered with

CaPre 2g (-18%, p=0.013) and 4g (-15%, p=0.039). Additionally 4-week treatment with 4g CaPre significantly lowered serum Apo-CIII by 25% ($p<0.01$) while 1g CaPre significantly increased serum Apo-AI by 17% ($p<0.05$).

Conclusions:
CaPre at daily doses of 1g-4g was effective in reducing serum triglycerides and increasing HDL-C without deleterious effects on LDL-C in mild-to-high hypertriglyceridemia patients. CaPre was safe, well-tolerated, with incidence of AEs similar to SOC (NCT01516151).