

The effect of insulin glargine and fish oil supplements on atherosclerosis progression

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A sub-study of the Outcome Reduction with an Initial Glargine Intervention (ORIGIN) trial, designed to investigate the effect of insulin glargine and omega-3 fatty acids on atherosclerosis progression, has found that, compared to standard care, only insulin glargine (a long-acting insulin) had a "modest" statistically non-significant reducing effect on the primary outcome of rate of change in maximum carotid intima media thickness (CIMT) at 12 carotid sites.

However, while [insulin](#) glargine did significantly reduce the secondary outcomes of the study (the annualised rates of change in maximum CIMT for the common carotid artery and for the common carotid plus bifurcation sites), there was no differences in either the primary or secondary outcomes between the omega-3 polyunsaturated [fatty acid supplements](#) and placebo groups.

"Our study demonstrates that in high-risk people with established cardiovascular disease or with [cardiovascular risk factors](#) plus type 2 diabetes or pre-diabetes, insulin glargine modestly retards the progression of atherosclerosis," said first investigator Professor Eva Lonn, Professor of Medicine and Population Health Research Scientist at McMaster University, Hamilton, Ontario, Canada.

As background to the trial, known as the Glucose Reduction and Atherosclerosis Continuing Evaluation Study (GRACE) study, Professor Lonn explained that the effects of treatment with insulin titrated to normalise fasting [plasma glucose levels](#) and with omega-3

polyunsaturated fatty acid supplements ([fish oil supplements](#)) on atherosclerosis progression in people with type 2 diabetes or pre-diabetes are unknown.

The GRACE study assessed the effects of insulin glargine and omega-3 [fatty acids](#) by performing yearly high-resolution carotid ultrasound examinations for five years and detailed [precise measurements](#) of CIMT. Patients were recruited from 32 centers in seven countries. At baseline patients' mean age was 63 years, over 50% had a history of prior heart attack, stroke or revascularisation, 80% had hypertension, 60% abnormal cholesterol and 10% were current smokers. About 90% had type 2 diabetes and 10% had pre-diabetes.

Most patients were receiving several therapies aimed at reducing their risk for atherosclerosis and its complications. Use of these drugs increased over the duration of the study, so that at study end 52% were on statins, 75% on ACE inhibitors or ARBs, 55% on beta-blockers and 70% on aspirin. Patients received open label insulin glargine targeting normal glucose levels or standard glycemic care, and double-blind therapy with a 1 gram per day supplement of [omega-3 fatty acids](#) or placebo. Median follow-up was five years.

Insulin glargine significantly lowered fasting plasma glucose, glycated hemoglobin and triglyceride levels and provided overall "excellent" glycemic control, said Professor Lonn, while omega-3 fatty acid supplements had no significant effect on glycemia or on lipid levels. Both interventions were safe.

Compared with the standard glycemic care, insulin glargine reduced the primary CIMT outcome, but the difference was not statistically significant (difference = 0.0030 ± 0.0021 mm/year; $p=0.145$) and significantly reduced the secondary outcomes (difference = 0.0033 ± 0.0017 mm/year; $p=0.049$ and 0.0045 ± 0.0021 mm/year; $p=0.032$).

There was no beneficial effect of omega-3 polyunsaturated fatty acid supplements on either outcome.

"These findings support the cardiovascular safety of this intervention," said Professor Lonn, "and suggest that longer term treatment with insulin glargine might prevent cardiovascular events. In the parent ORIGIN trial [insulin glargine](#) had a neutral effect on cardiovascular events over 6.2 years. Whether longer-term therapy may result in clinical event reduction remains currently unproven."

"The neutral effect of omega-3 polyunsaturated fatty acid supplements on atherosclerotic vascular disease is also concordant with the neutral effect on clinical cardiovascular effects in the parent ORIGIN trial. Some, but not all, previous studies reported beneficial effects of omega-3 polyunsaturated fatty acid supplements in cardiovascular event prevention and several large ongoing trials are still evaluating this question. Our study does not address the current recommendations to consume more fish, which may have health benefits not conferred by fish oil supplements."

Provided by European Society of Cardiology

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