Atorvastatin in Factorial with Omega-3 EE90 Risk Reduction in Diabetes (AFORRD): a randomised controlled trial.

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AIMS/HYPOTHESIS: The aim of the study was to examine the impact of statin or omega-3-acid ethyl esters 90 (omega-3 EE90; omega-3-acid ethyl esters 90 refers to a mixture of ethyl esters of n-3 fatty acids) on estimated cardiovascular disease (CVD) risk in community-based people with type 2 diabetes but without known CVD and not taking lipid-lowering therapy. METHODS: A central computer randomised 800 patients in 59 UK general practices to atorvastatin (n = 401, 20 mg/day) or placebo (n = 399) and omega-3 EE90 (n = 397, 2 g/day) or placebo (n = 403) in a concealed factorial manner. Participants with LDL-cholesterol <2.6 mmol/l, triacylglycerol <1.5 mmol/l and estimated 10-year CVD risk <20% were compared at 4 months. RESULTS: Mean (SD) age was 63.5 (11.7) years, HbA(1c) 6.9 (1.1) % and known diabetes duration (median [interquartile range]) was 4 (2-8) years. Fifty-seven per cent were men, 90% white and 74% had an estimated 10-year CVD risk ≥20%. Of 732 patients with 4-month data, more allocated atorvastatin (n = 371) compared with placebo (n = 361) achieved LDL-cholesterol <2.6 mmol/l (91% vs 24%, p < 0.001) and had estimated 10-year CVD risks <20% (38% vs 26%, p < 0.001). No differences were seen between those allocated omega-3 EE90 (n = 371) compared with placebo (n = 361) for participants achieving triacylglycerol <1.5 mmol/l (65% vs 60%, p = 0.18) or estimated 10-year CVD risks <20% (34% vs 30%, p = 0.18). There were no side effects of note. CONCLUSIONS/INTERPRETATION: Many community-based diabetic patients without known CVD remain at high CVD risk despite statin treatment and require additional risk-reduction strategies. The impact of omega-3 EE90 on CVD risk will remain uncertain until clinical endpoint trial results are available.