

AFORRD: a multi-centre trial evaluating potential cardiovascular risk reduction in patients with type 2 diabetes randomised in a factorial design to atorvastatin and/or omega-3 polyunsaturated fatty acids

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The Atorvastatin in Factorial with Omega-3 fatty acids Risk Reduction in Diabetes (AFORRD) study is a one-year, community-based, multi-centre, randomised controlled trial assessing the degree to which a statin and/or omega-3 polyunsaturated fatty acids (omega-3 PUFA) can reduce the risk of cardiovascular disease (CVD), as estimated by the UKPDS Risk Engine, in Type 2 diabetes. A total of 66 general practices are randomising 1,000 participants without a history of CVD in a two-by-two factorial design to 20mg atorvastatin or placebo and, simultaneously, to 2g Omacor or olive oil. After four months, all participants receive, double-blind, an additional 20mg atorvastatin (if estimated ten-year CVD risk >20%) or placebo. General practices are cluster randomised 50:50 to conventional management or to a behavioural intervention designed to improve therapy adherence. AFORRD, which will report in 2007, is assessing the proportion of type 2 diabetic people without CVD likely to require lipid-lowering therapy by current guidelines, the extent to which a fixed dose of a statin can reduce estimated ten-year CVD risk to <20%, the impact of 2g/day omega-3 PUFA on triglyceride levels and the degree to which therapy adherence can be improved by simple patient-centred behavioural techniques.