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People with Type 2 Diabetes who 'don't need' statins get significant benefit from intensive lipid lowering

Results of AFORRD trial presented at International Diabetes Federation World Diabetes Congress (IDF), Cape Town, South Africa

Results from a UK study by Oxford University have shown that patients not considered by their physicians to be at high enough risk for statin therapy benefit significantly from the intensive lipid lowering, as recommended by the latest cardiovascular disease (CVD) guidelines.

AFORRD (A^torvastatin in F^actorial with O^{mega}-3 fatty acids Rⁱsks R^eduction in Dⁱabetes) was a real world primary care study of 800 people with type 2 diabetes which aimed to assess the degree to which a statin and/or omega-3 fatty acids affect the lipid profile and the estimated risk of CVD. Despite recruiting patients not considered to be at high enough CVD risk to warrant statin treatment by their GP, it was found that 74% of the population were actually at high estimated CVD risk (>20% over 10 years), and 94% were at moderate to high risk (>10% over 10 years).

In these patients, lipid lowering with atorvastatin 20mg (trade name Lipitor) reduced LDL-cholesterol to ≤ 2.6 mmol/l in 91% of patients (mean 1.8mmol/l) and significantly reduced the estimated 10-year CVD risk by 21% (absolute risk reduction 6.7%).

'The study shows that the majority of people with type 2 diabetes in primary care are at higher cardiovascular risk than previously thought,' commented Professor Andrew Neil, Co-Principal Investigator of the study. 'The new guidelines from the Joint British Societies recommend statin treatment for the majority of people with type 2 diabetes, treating to a LDL-cholesterol target of 2mmol/l. However, this advice was based on outcomes trials which recruited patients mainly in secondary care and who were at enhanced CVD risk. AFORRD shows that intensive lipid lowering for most people with diabetes is the right approach for primary care too.'

Professor Rury Holman, Co-Principal Investigator added: 'Although statin treatment is important, for many patients lipid lowering therapy alone may not reduce their CVD risk sufficiently, and additional risk reduction strategies still need to be considered.'

AFORRD also examined whether a pharmaceutical preparation of highly-purified fish oil (Omega-3 EE90, trade name Omacor) reduced blood triglyceride levels. High triglycerides are thought to increase the risk of CVD. In the study, omega-3 EE90 reduced the level of triglycerides in the blood by 5.6 per cent but there was no reduction in estimated CVD risk. However, the researchers point out that fish oils may reduce CVD risk in others ways, and further work is needed to find out more about their potential benefits.

Full results of the AFORRD study will be published next year.

For more information please contact:

Press Office
University of Oxford
01865 280532
ruth.collier@admin.ox.ac.uk

Notes for Editors

*The **A**torvastatin in **F**actorial with **O**mega-3 fatty acids **R**isk **R**eduction in **D**iabetes (**AFORRD**) study is a one-year, community-based, multi-centre, randomised controlled trial assessing the degree to which a statin and/or omega-3 fatty acids reduce the estimated risk of cardiovascular disease in 800 people with Type 2 diabetes. See www.dtu.ox.ac.uk/aforrd

AFORRD protocols: 800 patients from 59 UK practices are randomised in a two-by-two factorial design comparing fixed doses of atorvastatin (Lipitor 20 mg per day) with placebo and, simultaneously, omega-3 fatty acids (Omacor 2 g per day) with a comparator (olive oil). Ten-year cardiovascular disease risk will be estimated using the UKPDS Risk Engine at entry, at four months and at one year. Patients whose estimated cardiovascular disease risk remains greater than 20 per cent at four months will receive an additional tablet containing 20 mg atorvastatin whilst the remainder will receive an additional placebo tablet, in double-blind fashion.

*The AFORRD trial has been designed and developed by the University of Oxford Diabetes Trials Unit in an academic collaboration with Pfizer UK. The data arising from the trial will be owned, independently analysed and published by the Diabetes Trials Unit. Pfizer UK (www.pfizer.com) provides funding, logistical support and atorvastatin (Lipitor) study medication, and Pronova (www.pronova.com) supplies omega-3 polyunsaturated fatty acids study medication (Omacor).

*The UKPDS Risk Engine is a type 2 diabetes specific risk calculator based on 53,000 patient years of data from the UK Prospective Diabetes Study (a 20-year trial which recruited 5,102 patients with type 2 diabetes, led by Professor Holman). See www.dtu.ox.ac.uk/index.php?maindoc=/ukpds/index.php

*The Diabetes Trials Unit (DTU), founded in 1985 by Professor Holman, is one of the largest European clinical diabetes research groups. It is based within the Oxford Centre for Diabetes, Endocrinology and Metabolism, part of Oxford University. The DTU investigates the pathophysiology of type 2 diabetes, evaluates potential therapeutic and preventative treatments and runs several multi-centre clinical-outcome studies including AFORRD, the Treating To Target in type 2 diabetes study (4-T) and the UK Prospective Diabetes Study (UKPDS). See www.dtu.ox.ac.uk

*OCDEM (the Oxford Centre for Diabetes, Endocrinology and Metabolism) is a pioneering centre at Oxford University which combines clinical care, research and education in diabetes, endocrine and metabolic diseases. By promoting world-class research, it aims to enhance understanding of these diseases and to accelerate the search for new treatments and cures. See www.ocdem.ox.ac.uk

*The International Diabetes Federation runs the 19th World Diabetes Congress, which is held in Capetown, South Africa, 3–7 December 2006. The International Diabetes Federation (IDF) is the only global advocate for people with diabetes and their healthcare providers. It is a non-governmental organization in official relations with the World Health Organization. The IDF's mission is to promote diabetes care, prevention and a cure worldwide. It is an umbrella organization of over 190 diabetes associations in more than 150 countries. See www.idf.org