

Issued on behalf of the  
International Steering Committee of the  
Anglo-Scandinavian Cardiac Outcomes Trial

For Immediate Use  
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## **Atorvastatin shown to decrease heart disease and stroke in patients with hypertension and low cholesterol**

A major European trial studying different blood pressure treatments and the effects of additional cholesterol lowering, announces today that it has stopped part of its trial earlier than expected because results collected already show a significant benefit to patients on one of its treatments.

It found that among 10,297 patients with hypertension and cholesterol levels lower than currently recommended for treatment, those given the cholesterol-lowering drug atorvastatin suffered significantly less heart attacks and strokes compared to those receiving the placebo treatment.

The International Steering Committee of the independent Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) have stopped the relevant part of the trial and informed fellow investigators, their patients and the regulatory authorities about the newly emerged results.

The rest of the trial, which compares different blood pressure treatment strategies, will continue unchanged.

"The trial shows that patients with high blood pressure but low cholesterol benefit clearly from taking a statin. It is too early to quantify the precise size of the effect, but we expect to see a reduction in heart attacks of about one-third among those taking a statin," say ASCOT study co-chairmen Björn Dahlöf from the Sahlgrenska University Hospital, Östra, Sweden and Peter Sever from Imperial College London, UK.

"However the ASCOT trial still continues and we wish to make it clear to all our patients that this new information does not mean they should stop the tablets they are taking. It is vital that all patients on the trial carry on with their treatment regimens," they add.

All patients will be recalled to visit their ASCOT doctors and will be examined again in the coming weeks

Members of ASCOT's Data Safety Monitoring Board, who work independently of the trial investigators and are the only researchers permitted to look at the results of the five-year old trial while it is ongoing, reported their findings to the ASCOT International Steering Committee on 2 September 2002.

They described a highly significant reduction in the number of heart attacks and a significant reduction in the number of strokes experienced by those patients receiving atorvastatin compared to placebo.

As the size of the benefit exceeded the stopping rules for this part of the trial, the Data Safety Monitoring Board's recommendations to close this section of the study were accepted by the ASCOT Steering Committee. This part of the study was formally closed on 1 October 2002 but data collection relating to it is expected to continue until the end of December 2002.

Further announcements about the results of the atorvastatin part of the trial will be made in 2003, with final results of the whole ASCOT study expected in 2004.

Patients were only eligible for the cholesterol lowering part of the trial if they had a blood cholesterol level of 6.5 mmol per litre or less - a significantly lower range of cholesterol levels than is usually treated by doctors. This part of the trial is specifically aimed to discover if a statin would confer additional protection against coronary heart disease in hypertensive patients with low cholesterol levels.

The other primary objective of ASCOT is to compare a new treatment strategy for hypertension against an old one, and discover which is better at preventing heart attacks.

The new treatment is a calcium channel blocker (amlodipine), to which in the majority of patients the angiotensin converting enzyme inhibitor, perindopril, is added to achieve the goal blood pressure. The older treatment is a beta blocker (atenolol), to which in the majority of patients a diuretic, bendrofluazide, is added to achieve goal blood pressure.

By May 2000, 19,342 patients had been entered on the trial and randomly selected to receive one of the two blood pressure lowering strategies. Out of the trial total 10,297 patients with low cholesterol were also randomised to receive either placebo or atorvastatin.

Patients in the trial are aged between 40 and 79 years old, with high blood pressure and have at least three other pre-specified cardiovascular risk factors.

The primary endpoint of the trial is either a heart attack from which the patient survives or death from coronary heart disease. A large number of other

cardiovascular events including stroke are identified as secondary endpoints in the study.

The principal sponsor of ASCOT is Pfizer Inc, New York. Support has also been provided by Servier Research Group, Paris and Leo Laboratories, Copenhagen.

### **About ASCOT**

Launched in 1997, the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) is an independent, investigator-led study aiming to evaluate different treatment strategies to prevent cardiovascular disease in hypertensive patients.

It is being conducted in over 700 general practices and regional medical centres across the UK, Ireland and the five Nordic countries, Sweden, Finland, Denmark, Norway and Iceland.

Number of patients on the ASCOT trial by country

Denmark (including Iceland) -- 1,567

Finland -- 2,382

Norway – 2,226

Sweden – 4,069

UK and Ireland – 9,098

TOTAL – 19,342

With over 19,000 patients across the UK, Ireland and Scandinavia, ASCOT is the largest European based prospective, randomised hypertension trial ever to be conducted.

It is jointly coordinated by Imperial College London (Cardiovascular Studies Unit, Department of Clinical Pharmacology, St Mary's Hospital, London) and Göteborg University (Scandinavian CRI), Sweden.

ASCOT web site: [www.ascotstudy.com](http://www.ascotstudy.com)