

End of the road for aliskiren in heart failure

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A subgroup analysis in heart failure patients with diabetes from the ATMOSPHERE trial has failed to show benefit and signals the end of the road for aliskiren in heart failure. The findings were presented for the first time today in a late breaking trial session at Heart Failure 2016 and the 3rd World Congress on Acute Heart Failure.

"This was a [subgroup analysis](#) with the inherent limitations of this type of study. It failed to show superiority or non-inferiority of aliskiren over the angiotensin-converting enzyme (ACE) inhibitor enalapril in heart failure [patients](#) with diabetes," said principal investigator Professor Lars Kober, a consultant cardiologist at Rigshospitalet - Copenhagen University Hospital in Copenhagen, Denmark.

He continued: "The result may have been positive had the European Medicines Agency (EMA) not asked us to withdraw patients with diabetes from the trial. We will never know, as the angiotensin receptor neprilysin inhibitor LCZ696 has since emerged and bypassed the need for aliskiren."

Aliskiren is a renin-angiotensin-aldosterone system inhibitor that is used in patients with hypertension. The Aliskiren Trial of Minimizing OutcomeS for Patients with HEart failure (ATMOSPHERE) included 7016 patients with heart failure and reduced left ventricular ejection fraction, of whom 2340 were randomly assigned to enalapril plus aliskiren, 2340 to aliskiren, and 2316 to enalapril. Of these, 1944 (27.7%) had diabetes and 5072 (72.3%) were non-diabetics. The main study results were published in April and showed that aliskiren was not

superior or non-inferior to standard treatment with an ACE inhibitor.²

Following the results of two separate [trials](#), the EMA requested the withdrawal of all patients with diabetes from ATMOSPHERE. The Aliskiren Trial in Type 2 Diabetes Using Cardiorenal Endpoints (ALTITUDE) had been stopped after patients with diabetes and a high risk of cardiovascular events were found to have an excess risk of cardiovascular and renal events with aliskiren. The Aliskiren Trial on Acute Heart Failure Outcomes (ASTRONAUT) had found a tendency towards harm in patients with diabetes.

The current study is a prespecified subgroup analysis of ATMOSPHERE according to baseline diabetes status. Due to the premature withdrawal of patients with diabetes from the study drug, median follow-up was shorter in those with diabetes than those without (24.1 months versus 46.0 months; p

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