Angioplasty and Stent for Renal Artery Lesions trial (ASTRAL)

The ASTRAL trial opened in September 2000 and closed in October 2007 having recruited 806 patients, making it by far the largest trial in atherosclerotic renovascular disease (ARVD). ARVD is a long-term progressive condition, so it is important not just to look at the short-term impact of revascularisation but to determine whether it has long-term benefits for patients.

Approval gained for long term ASTRAL follow-up

The ASTRAL trials team now have ethical approval to follow up all patients in ASTRAL for longer. Patients will now be followed-up annually for 10 years from the date the last patient was randomised i.e. to 26th Oct 2017. (The protocol previously stated that patients would be followed up for 5 years from randomisation). As part of patient's standard care they would be recalled annually for clinic visits. This will permit not only reliable evidence on the long-term effects of revascularisation on renal function and long term blood pressure control to be obtained, but will also allow investigation of its impact on major clinical end-points, such as need for dialysis and renal transplantation (which can have large cost-implications), vascular events and mortality.

Better research into the natural history of ARVD – e.g. relationship between baseline parameters (such as level of proteinuria and level of renal function and rate of progression) – will be possible with long-term follow-up and the ASTRAL trial provides a unique opportunity to follow-up a cohort of patients with ARVD over a long period of time, including to investigate if there are subgroups of patients who may benefit from revascularisation.

ASTRAL Results Published

The ASTRAL results have now been published in the New England Journal of Medicine on the 12th November 2009. Please follow the link below to view the publication:

Revascularisation versus Medical Therapy for Renal-Artery Stenosis - N Engl J Med 2009 (http://www.nejm.org/doi/full/10.1056/NEJMoa0905368)

What is ASTRAL?

Balloon angioplasty and/or endovascular stenting are being used increasingly often among patients with atherosclerotic renovascular disease (ARVD). Although these procedures do result in obvious improvements in arterial patency, there is currently no good evidence that they delay progressive decline of renal function. However, since revascularisation is associated with a definite procedural risk, such a procedure might not be justified if the benefits to renal function were small and outweighed by the procedural hazards.

The ASTRAL trial is designed to address the issue of whether renal arterial revascularisation with balloon angioplasty and/or endovascular stenting can safely prevent progressive renal failure among a wide range of patients with ARVD. Approval has been gained for long term ASTRAL follow-up.

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