PAVE the way to a better quality of life on haemodialysis

The PAVE Trial (Paclitaxel assisted balloon Angioplasty of Venous Stenosis in haEmodialysis access) is a randomised controlled trial which aims to preserve arteriovenous fistulae (AVF), used for haemodialysis. We plan to start recruiting haemodialysis patients from Guy's hospital and it's satellite units in October 2015.

Vascular access for haemodialysis

Haemodialysis requires access to the circulation and the best option for this is AVF, which is made by surgically joining an artery and a vein. However, these AVFs have a limited life and may develop narrowed segments. This can lead to thrombosis (blockage), which may result in admission to hospital and the insertion of temporary dialysis lines which are prone to infection. The standard treatment for the narrowed segments is to use a special balloon to stretch the segment. This is done in the X-ray department. Unfortunately, the benefit often does not last long and the narrowing can return.

PAVE trial

The aim of the PAVE trial is to test whether using a drug-coated balloon can delay the return of the narrowing and keep the AVF in use for longer. This could lower the number of hospital admissions and repeat procedures needed.

The trial is funded through the National Institute for Health Research (NIHR), with the balloons provided by a company called Bard. King's College London together with Guy's and St Thomas' NHS Foundation Trust co-ordinate the trial.

The facts

Participants in the trial will be randomly placed into one of two groups. Immediately after treatment with the standard balloon that is normally used, one group will receive another treatment with the drug-coated balloon and the other group will receive another treatment with a balloon which is not drug-coated. Participants will then be followed up for at least one year.

The two groups can then be compared to see if the AVFs of participants in one group last longer than those in the other group. The trial will gather evidence of the safety and potential benefit of using the drug-coated balloon. The outcome of the trial will be evidence to identify the best method to use, so that we can safely improve patients' quality of life on dialysis.

We will recruit 211 patients, who are receiving haemodialysis, from 6 kidney units across the UK. The chief investigator is the nephrologist Michael Robson, the lead surgeon is Frances Calder, and the lead radiologist Narayan Karunanithy. These three doctors are all based at Guy's hospital. There is a safety committee of experts who will check the data and ensure that no patient is placed at risk.

For more information about the PAVE trial, please contact Vikki Semik, the PAVE Clinical Trial Manager, at vikki.semik@kcl.ac.uk.

NHS
National Institute for Health Research

This project is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership