

1 The PITHIA Trial

The PITHIA trial is a clinical trial based in the UK that aims to evaluate pre-implantation kidney biopsies as a tool to help increase the number and quality of kidneys transplanted.



There is a great shortage of kidneys for transplantation. All kidneys from deceased donors carry risk to the recipient (risk of not working, or of disease transmission), but donor age is strongly associated with poor function and early failure of the kidney transplant. This is important, because the majority of the pool of potential UK deceased donors are now over 60 years old. Thus, if we can improve our identification of kidneys from older donors that are better 'quality', we can maximize numbers of transplants performed without compromising transplant outcomes.

The use of urgent kidney biopsy (analysis of a small portion under the microscope) to identify age-related damage has been reported to aid selection of those kidneys from older donors that are good enough 'quality' for transplantation. This approach has not been widely adopted in the UK, because the exact impact that the extra information provided by biopsy has on transplant numbers and on transplant outcomes is not clear, and its cost effectiveness remains unproven.

Our study will evaluate whether providing an urgent 24 hour National Biopsy Service increases the number and function of kidneys transplanted from donors aged over 60 years. The study is a national trial: every 4 months a randomly-chosen group of UK kidney transplant centres will be offered access to the National Biopsy service (a 'stepped-wedge randomised cluster trial'). By the end of the trial, all 22 UK centres will have access (see figure 1), and we will then compare results for each centre from before and after the biopsy service was made available as well as evaluating the cost of providing the service. We anticipate that this comparison will show that biopsy availability increases the use of kidneys from elderly donors by about 10%, which equates to an additional 150 kidney transplants performed in the UK each year.

The National Institute for Health Research have agreed to fund the trial, and we anticipate that it will start in the Autumn of 2017. We hope that the NKF will be able to help in a few ways: firstly, we will be visiting all the participating kidney transplant centres before the service is introduced. This will be to help advise the units about how to use the biopsies. We would like to have good patient representation in these meetings to help advise their transplant clinicians about what their views are about the acceptable risks of the kidney transplants. In addition we want to publicise the biopsy service as much as possible so that patients understand how the biopsy might be used to help evaluate the transplant when they are called in. We would like to contribute to NKF publications and will make contact with individual groups before we plan to make the visits. (<http://www.pithia.org.uk>). Contact Dominic Summers (dms39@cam.ac.uk) or Gavin Pettigrew (gjp25@cam.ac.uk) for more information.

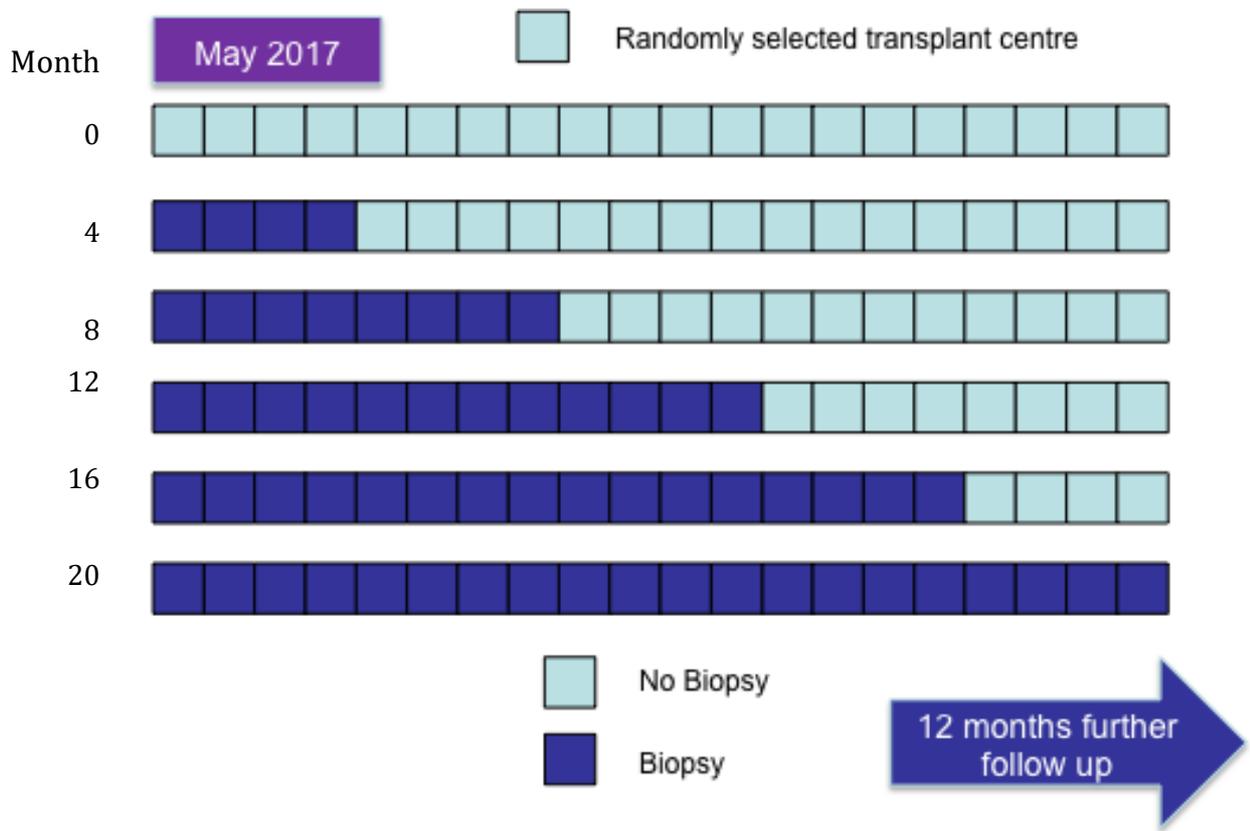


Figure 1.1 - The Stepped-Wedge Cluster design