



Clinical Trials Unit Long Road Cambridge CB2 0PT

<u>Pre-Implantation Trial of Histopathology In renal Allografts</u>

28th September 2018

Dear Kidney Patient Associations,

We are writing to inform you about a new clinical trial for kidney transplantation – which is called the PITHIA trial. All the kidney transplant centres in the UK are taking part in this trial and it will introduce a national biopsy service (for the assessment of kidneys, prior to transplantation, from deceased donors aged 60 years or older). A biopsy is where a small sample of the kidney tissue is taken so that it can be examined under a microscope. This biopsy will happen at the donor hospital and **before** the kidney is transplanted.

Why are we doing the PITHIA trial?

The aim of PITHIA is to allow doctors to perform higher numbers of good quality transplants using kidneys from older donors. Many potential kidney transplants are from donors aged 60 years or older, and many of the kidneys from these donors are not used (due to worries about how these kidneys may work). But we are aware that age alone is not a good predictor of kidney health and so many good kidneys may be discarded rather than transplanted. The PITHIA trial will allow doctors to look at each kidney in more detail (using a biopsy). The biopsy service will hopefully allow doctors to identify more good kidneys for transplantation.

Key points:

- Doctors will be providing information about the trial to patients on their kidney transplant waiting list.
- Not all kidneys (from donors aged 60 years or older) will be biopsied this will only be performed where the transplant surgeon thinks it is necessary.
- The biopsy will take place before the recipient is called into hospital.
- If a biopsy has been performed on a kidney, this will be discussed with the recipient before they consent for the operation.
- This trial does not affect the recipient's right to decline any organ that they feel is inappropriate.

The trial will start on 1st October 2018 and will last for two years. Every four months a randomly-chosen group of UK kidney transplant centres will be given access to the national biopsy service (PITHIA is a 'stepped-wedge cluster randomised trial'!). We will inform your group again once your local transplant centre has the biopsy service.

By the end of the trial, all centres will have the biopsy service, and we will then compare the transplant activity for each centre from before and after the biopsy service was made available. We anticipate that this comparison will show that biopsy availability increases the use of kidneys from donors aged 60 years or older by about 11% (which would mean an additional 120 kidney transplants could be performed in the UK each year). If the trial results show that biopsies are beneficial, we will present the case to the National Health Services (England, Scotland, Wales, Northern Ireland) to request funding for pre-transplant biopsies – so that they become standard practice.

Biopsies are already in routine use at Addenbrooke's Hospital (Cambridge), which has provided the evidence-base for the PITHIA trial.

We would appreciate it if you could help us by sharing this information with all members of your support group, and on social media where appropriate. Further information about the trial can be found on the website (www.pithia.org.uk) or by contacting PITHIA@nhsbt.nhs.uk.

Thank you for your support.

Kind Regards,

Gavin Pettigrew Chief Investigator Emma Laing Trial Manager

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ASSESSMENT IN
TRANSPLANTATION

www.pithia.org.uk