The 3C Study

Campath, Calcineurin inhibitor reduction and Chronic allograft nephropathy

The 3C Newsletter *Summer 2011*

Welcome to the first edition of the 3C NEWSLETTER and thank you for your interest and participation in the 3C study. This newsletter will endeavour to keep you informed about progress on the trial and hopefully entertain you along the way.

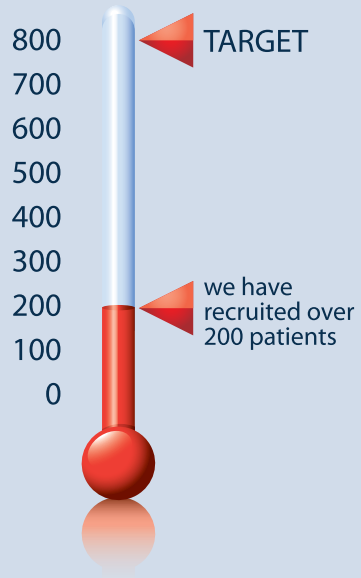
Who are we?

In each of the newsletters we will introduce you to different members of the team. The person in the picture is Professor Peter Friend from the University of Oxford. He is the Professor of Transplantation at Oxford and has been visiting transplant centres across the United Kingdom, inviting them to join the study and thus unite all those people working in transplantation in a collaborative effort. We hope there will be many national studies in transplantation to follow after 3C.

Professor Peter Friend

Recruitment hits 200

The first patient in 3C was randomised in Oxford in October 2010. Since then we have recruited over 200 patients from 12 hospitals including Cardiff, Edinburgh, Leeds, Royal Free Hospital, Plymouth, Sheffield, Manchester, Glasgow, Portsmouth, Nottingham and Cambridge. The hard work is not over as we aim to recruit 800 patients in the next two years and to do this we are working to start randomising patients at centres in Newcastle, Liverpool, the Royal London Hospital, Coventry and Birmingham.



Why are we doing the study and why is it called 3C?

Kidney transplant function inevitably declines over time. On average, after about 10 years the transplant "fails" and the recipient either receives another transplant or returns to dialysis. All people who receive a kidney transplant need drugs to prevent their body from "rejecting" the new kidney. Some of the standard medications used to prevent rejection (in particular, some drugs called "Calcineurin inhibitors") may also cause long-term damage to the kidney. The long term damage to the transplant kidney has a medical term called Chronic Allograft Nephropathy.

The 3C Study is testing two treatments which might reduce some of this long-term damage without risking rejection. The two drugs are called Campath and sirolimus. Using these drugs may enable the drugs that are very slowly damaging the transplanted kidney to be given in a lower dose or avoided completely. So the 3Cs are:

1st C = CAMPATH
2nd C = CALCINEURIN INHIBITOR REDUCTION
3rd C = CHRONIC ALLOGRAFT NEPHROPATHY

Second randomisation

Some of you will be approaching 6 months after you were randomized into the trial and received a transplant. At 6 months, when you visit for your routine follow-up, if there have been no problems with acute rejection or protein leaking from your kidney, you will be eligible for the second part of this study. If you and your doctor decide to go ahead, you will either continue on your current tacrolimus tablets or switch over to sirolimus. The decision to change treatment or not will be decided at random by our computer (like the toss of a coin). This second randomisation is how this study is able to test two drug treatments in one study.

Sirolimus (also known as rapamycin) was first discovered in bacteria called *Streptomyces hygroscopicus* and was isolated from a soil sample from Easter Island. Easter Island is also known as Rapa Nui, and hence the drug's other name rapamycin.

Plans for a website

For those of you that use the internet we are currently designing a website so that you can keep up to date with the progress of the trial day or night! The address will be: www.ctsu.ox.ac.uk/3c and we will let you know when it goes live.

The study coordinating centre can be contacted:

- **by telephone:** 24 hour Freefone service **0800 585323**; or
- **by telephone:** Weekday office hours - Ruth Davis **01865 743528**
- **by post:** Ruth Davis, Administrator, 3C Study, CTSU, Richard Doll Building, Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF; or
- **by e-mail:** ccc@ctsu.ox.ac.uk

Website

- **www.ctsu.ox.ac.uk/3c**

And remember that you can contact your local team, too.

Thank you very much for your participation in the 3C Study. We hope that trials like this one can improve the long-term outcomes for recipients of renal transplants for many years to come, so thank you for agreeing to take part.