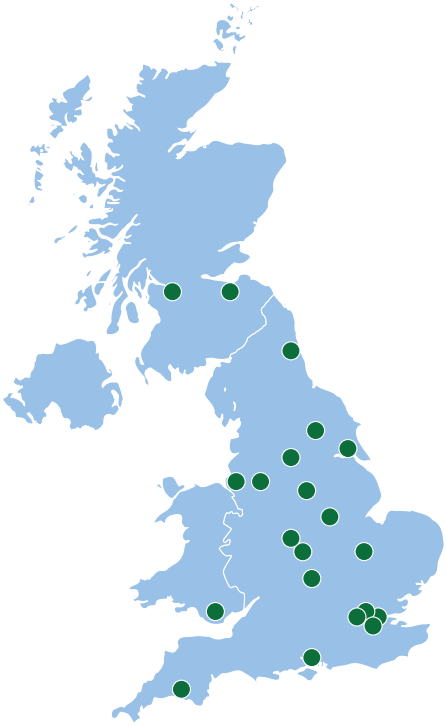
The 3C Study

Campath, Calcineurin inhibitor reduction and Chronic allograft nephropathy

The 3C Newsletter *Summer 2012*

Welcome to the second 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.

Where are we?



The 3C Study is coordinated by the University of Oxford's Clinical Trial Service Unit. 18 kidney transplant centres in the UK are now collaborating on the study and you can see where they are on the map. This collaboration of so many transplant centres is an excellent start to what we hope will be a series of national trials in kidney transplantation. Collaborations like this mean that in the future large trials can be set up and recruit rapidly so that important questions in the care of transplant recipients can be answered more quickly.

Why do we need randomised trials?

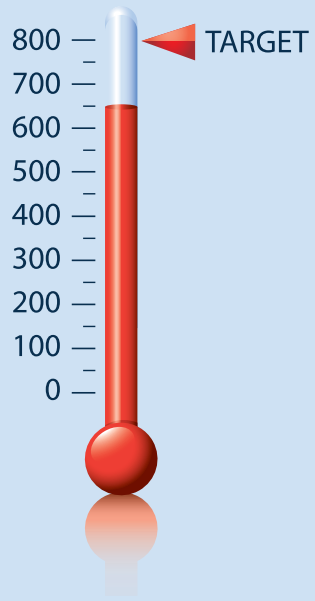
Many people wonder why it's necessary to do randomised trials in medicine. Every week there are press reports of studies that have looked at the medical records of many thousands of people and compared outcomes of people taking a certain drug with those of people not taking a drug. Such studies (called "observational" studies) don't involve randomisation, can be done quite quickly and are much less expensive than a randomised trial. So why bother with randomisation?

The reason is that randomisation is the only way to ensure that the groups you are comparing are the same in every way other than whether they are receiving the treatment you are interested in studying. Observational studies will always suffer from not being able to match their groups so well, which means that any effects they see might be either due to the treatment or to some other factor which they haven't been able to detect. Randomisation avoids this problem and therefore provides the best evidence in healthcare.

As well as being randomised, trials need to be large which is why we've gone to all the effort of recruiting so many participants. Whenever you do a study, there is always the possibility that the results you get are the play of chance. The smaller the study, the more prone it is. Therefore, we wanted to make 3C as large as possible so that the possibility of our results just being chance (rather than a true effect) is as small as possible.

Recruitment hits 650

We are well on our way to our target of 800 participants randomised into the 3C study. Our best month for recruitment was April 2012 when 58 participants entered the study. At the current rate we are hoping that we can finish our recruitment around the end of 2012. To recruit this many people in such a short time (just over 2 years) is a major achievement for UK transplantation, which would not have been possible without your help. So thank you!

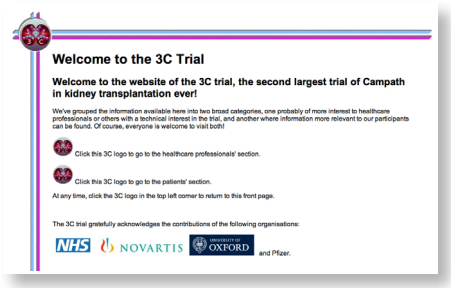


3C: two studies for the price of one!

In the 3C study, we are not trying to answer just one important question in kidney transplantation but two. You entered the study just before your transplant so that we could compare two "induction" treatments. These are antibody-based treatments given at the time of transplantation which aim to reduce the chance of your body rejecting your new kidney. We wanted to compare the current standard (basiliximab) with a treatment which has been around for many years called Campath. However, we didn't want to stop there. Given that we have gone to the trouble of recruiting so many participants, it would seem sensible to get as much out of the study as possible. That's why – 6 months after your transplant – we ask you and your doctors to consider another randomisation between the current standard "maintenance" treatment (tacrolimus, which you take every day) and another drug called sirolimus which works differently. With this design we hope that the 3C study will provide answers to two important questions in kidney transplantation which will benefit future kidney transplant recipients.

Our website

Have you visited the website? Visit it at **www.3cstudy.org** and you will find more information about the study and previous newsletters. You can now keep up to date with the trial day or night!



Keeping in touch

Many of you were transplanted over one year ago so have completed all the necessary visits with your study team in hospital (although your usual clinical follow-up will continue). We will soon be sending out questionnaires which we hope you will be happy to complete on an annual basis. The information we collect on these questionnaires will be crucial to getting a full and accurate understanding of the effects of the study treatments, so please do complete them. It shouldn't take long!

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.3cstudy.org**

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.