BHI Bristol Heart Institute

Clinical Trials and Evaluation Unit Newsletter

University of BRISTOL

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Clinical Trials Unit recognised nationally

We are pleased to announce that the Clinical Trials and Evaluation Unit has passed a rigorous national standard designed by the UK Clinical Research Collaboration (UKCRC) to improve the quality and quantity of expertise to carry out medical trials nationwide.

To apply for UKCRC registration, the Unit had to demonstrate:

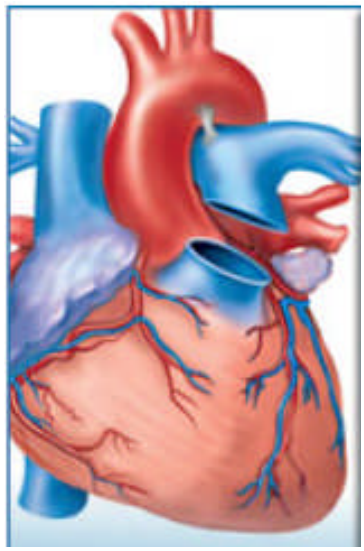
- it could run multi-centre trials and other studies,
- take overall responsibility for the design, conduct, data management and analyses, and publicity of research,
- ensure trials are run and reported in line with appropriate standards and regulations.

The Unit was among 14 across the country to be awarded provisional registration. This means we were judged to be developing the expertise for full registration but did not yet meet all criteria for infrastructure, resources and experience to gain full registration. A further review will take place in 2009 when it is hoped that full registration will be granted.

The UKCRC brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia to a UK-wide environment that facilitates and promotes high quality clinical research for the benefit of patients. If you would like to find out how you might be involved visit their web site at: http://www.ukcrc.org/patientsandpublic.aspx

Further research comparing on and off pump CABG surgery

We have recently been awarded a large grant by the Medical Research Council for a trial to compare on and off pump coronary artery bypass graft (CABG) surgery, i.e. surgery with or without the heart lung machine in patients with a high risk of complications after surgery. Several years ago we carried out the BHACAS studies which compared on and off pump surgery in patients with a low risk of post-operative complications. The BHACAS studies showed that off-pump surgery has advantages in the short-term, and that in the long-term, the quality of the grafts is good. Observational studies, i.e. those using data routinely collected about operations and in-hospital outcomes, suggest that high-risk patients may derive even more benefit from having off-pump CABG performed than the low risk group. The new trial will aim to recruit over 5000 patients from 20 hospitals in the UK and 20 hospitals abroad.



Can stem cells repair the heart after a heart attack?

Some of you may have seen in the news that we have been awarded a grant to investigate whether stem cells collected from patient's blood prior to cardiac surgery can be used to help repair the heart in areas where it has been damaged by a heart attack. The stem cells will be injected into the damaged area during cardiac

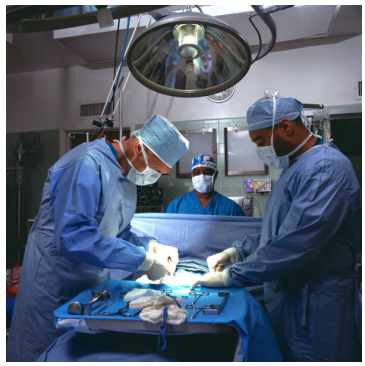
(Continued overleaf)

Stem cells *(Continued from front page)*

surgery. An echocardiogram will be used to look at how well the heart is contracting (scar tissue does not contract properly) before and after the operation.
To act as a comparison some patients will be injected with saline only (i.e. placebo), and during the trial neither the patient or the doctor assessing them will know which they have received. This is called a 'double blinded' randomised controlled trial and it is the most objective way of assessing a new treatment or procedure. The work is based on collaborative research between scientists and cardiac surgeons within the BHI.

New method for combined valve and CABG operations

Valve replacement surgery, unlike coronary artery bypass grafting (CABG), has to be performed on-pump (i.e. the heart is stopped and the blood is pumped around the body by the heart lung machine). This is because valves are on the inside of the heart and the heart must be cut open to access them. We are recruiting patients to a trial that compares doing the entire operation on-pump, with operations where the CABG component is performed off-pump, and then the heart lung machine is only used for the valve replacement part of the operation. The latter group will have less time on-pump, and we will be comparing the frequency of postoperative complications between the two groups, hoping that they will be reduced using the new method.



Investigating who really needs a blood transfusion

The TITRE trial examined the effect of lowering the haemoglobin threshold used for deciding who needs a transfusion. Patients can be given blood for a number of reasons, but we concentrated on the blood haemoglobin threshold, i.e. the level of anaemia allowed before blood is transfused. Patients were randomised between the standard threshold and a slightly lower one, to examine the effect of a more stringent transfusion criterion. We expected a lower frequency of transfusions in the stringent criterion group compared to standard practice. The most striking result was that the number of people receiving a blood transfusion in both groups were lower than expected, i.e. even those who were randomised to have the usual threshold for transfusion were less likely to receive a transfusion than those outside the trial.

We compared the rates of serious complications between the groups and found no evidence of a difference, although this was only a pilot study and there may not have been enough patients for us to detect differences in serious complications which tend to be rare. The results of this study have been used to help plan a multicentre study which should give a definitive answer to the question of whether the transfusion threshold can be safely lowered.

Cardiac support groups

If you are interested in joining a cardiac support group in your area, the British Heart Foundation has about 300 affiliated groups in England and Wales. Activities vary from group to group, but may include a listening service, exercise classes or invited speakers on a wide range of topics. For more information about groups in your area, please contact the BHF Cardiac Care Administrator on 0207 487 7110 or if you have access to the internet you can use their Website: www.bhf.org.uk

British Heart Foundation

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