



# TAPS

## **Transfusion Alternatives Pre-operatively In Sickle Cell Disease** **Randomised Controlled Trial**

Are the benefits of a pre-operative transfusion outweighed by the risks of transfusion in Sickle Cell patients (HbSS or HbS/ $\beta^0$ thal) having low or medium risk planned surgery? The TAPS trial aims to answer this question, and is recruiting patients now.

### **Why is this clinical trial needed?**

For many years doctors have been trying to find the best way to prepare sickle cell patients before they have surgery. Patients have often been given a simple 'top-up' or exchange transfusion of red cells before they have an operation in the belief that this will help their recovery afterwards. A large study was done in the USA in 1995 which found that patients undergoing many operations did equally as well if they had a top-up transfusion rather than an exchange. This study influenced the way patients were treated all over the world, with fewer patients having exchange transfusions than before.

In the last few years doctors have been finding that some patients appear to recover from their surgery just as well if they don't have a transfusion before their operation at all. The TAPS trial is a new large scale study which will show us whether or not a transfusion before surgery is needed in sickle cell patients. Patients are randomly allocated either to have a blood transfusion before surgery, or to have their surgery without any planned transfusions before. Patients can still be transfused during or after their surgery if their doctor decides they need to be. Information is being collected from all patients on how quickly they recover from surgery, and whether there were any sickle problems or infections. The results from the transfused and untransfused patients will then be compared. Finding out whether a pre-operative transfusion is needed before surgery will enable doctors to provide the best care for sickle patients in the future.

### **Patients who can join the trial**

Patients aged 1 year and over with HbSS or HbS/ $\beta^0$ thalassaemia who are having a planned operation may be eligible to join the study. Most types of operation are included, apart from emergency operations and major surgery on the brain and heart. We are not including patients with HbSC because a survey done by the National Blood Service in 2003 showed that most of these patients are not given a blood transfusion before they have an operation.

### **Your protection**

The study has been designed by doctors, nurses and patient representatives who understand what having sickle cell means. They have taken into account the type of operations you have, the complications you might have with surgery and looked carefully into the best way to design our study to make sure that it is a collaboration between patients and the doctors and nurses at the hospitals you attend. Hospitals will identify suitable patients who will be offered a patient information leaflet to read which tells them all about the study. Someone will be on hand to answer any questions patients have before they decide whether to join in. No one can be entered into the study without having given written consent either for themselves or their child. The trial will be overseen by an independent group of doctors who will make sure the trial is going well and recruiting enough patients. Dr Asa'ah Nkohkwo, Chief Executive of the Sickle Cell Society, is on the Steering Committee.

### **Who is running the study?**

Professor Sally Davies and Dr Lorna Williamson are the joint Chief Investigators for this study, with Dr Jo Howard and Dr David Rees as Medical Experts. The National Blood Service (NBS)/Medical Research Council (MRC) Clinical Studies Unit based in Cambridge are running the study, and the funding comes from the National Blood Service.

### **Recruiting Hospitals are:**

St Thomas's Hospital  
(with Evelina Children's Hospital)  
Central Middlesex Hospital  
Manchester Royal Infirmary.  
St Mary's Hospital in Paddington  
Birmingham City Hospital  
Birmingham Children's Hospital  
Bristol Royal Infirmary  
(with Bristol Children's Hospital)

Kings College Hospital,  
University Hospital Lewisham  
Mayday Hospital in Croydon  
The Whittington Hospital  
North Middlesex Hospital  
Royal London Hospital  
Queen Elizabeth Hospital Woolwich  
North Middlesex Hospital

Approximately 5 or more hospitals are planning to join the study plus hospitals in the USA, Canada and Ireland. We are currently applying for permission to allow this to happen.

We will need 400 patients to give us a reliable answer whether sickle cell patients routinely need a blood transfusion before surgery. This might take 5 years - quicker if we have US patients too. We hope that by reading this on the Sickle Cell Society website you will help us to let as many people as possible know about the trial.

If you would like to know more about this project, or think you might be eligible for the trial and would like to take part please contact:

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