

VERBAL ASSENT SHEET TO INVITE PARTICIPATION IN THE CVLPRIT STUDY

“Complete Versus Lesion only Primary PCI Trial”

Version 6 (30th October 2010)

This should be read to the patients and the result of the discussion documented in the clinical notes

- Your doctors have diagnosed that you are having a heart attack, which means that it is likely one of the arteries in your heart is blocked reducing blood supply to your heart muscle.
- In this hospital the usual treatment is to open the blocked artery with a balloon and stent using a procedure called angiography in which a fine tube is passed into the heart.
- Sometimes more than one artery is blocked or narrowed. At the moment we do not know if you have only one blocked artery causing your heart attack, or you have another one which is narrowed or blocked.
- We are undertaking a research study to try and find out whether it is better to treat just the artery causing the heart attack (which is a routine approach in many centres), or to treat all the arteries that look narrowed or blocked at the same time.
- The title of the study is CVLPRIT (Complete Versus Lesion only Primary PCI Trial). If we find that you have more than one artery narrowed or blocked, we would like to invite you to take part in the study.
- If you agree, we will either treat only the blocked artery causing the heart attack or we will attempt to open all the affected arteries.
- Allocation to single artery or multiple artery treatment will be performed at random (rather like tossing a coin to make the comparison fair) as we do not know which treatment is better.
- We are also asking for your permission to record simple details of your health condition and treatments in our confidential research record as part of a “registry”.
- After you have had your early treatment and are recovering, we will provide you with further information about the study and you will have another opportunity to discuss this and decide if you wish to carry on in the study or not.

Whether you decide to take part or not is entirely up to you, and in any case you will receive the best care we can provide for your condition.