

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study to evaluate new ways of diagnosing and treating various diseases. A clinical trial is carefully conducted by physicians, researchers, and nurses to find treatments that work and ways to improve patients' health. Clinical trials are responsible for many new medications and procedures that help patients today that were not available just a short time ago.

At The Valley Hospital we have approximately 30 cardiac clinical trials open to participants who meet certain criteria for each study. More than 200 patients in clinical trials are currently being followed up by our board-certified cardiologists, cardiac surgeons, and research nurses. Just a few of the trials taking place at Valley include studies to evaluate new drug-coated cardiac stents, new medications, new methods in cardiac surgery, combinations of medications, heart valves, a registry to monitor patients, and studies to evaluate the quality of life of patients who receive pacemakers.

WHY PARTICIPATE IN A CLINICAL TRIAL?

There are several reasons:

- You can play an active role in your own health. Patients in clinical trials often receive the new therapy being evaluated and are monitored on a more frequent schedule to track the status of the therapy.
- You may receive a new treatment before it is widely available.
- You can help others by contributing to the information that is known about heart disease and its treatments.

WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

You have been asked to take part in a clinical trial because you meet certain guidelines for the trial. Every trial is different and has its own criteria about participants' age, gender, type of disease, previous treatment history, and other

medical conditions. These criteria are not meant to reject people personally, but to enroll the patients needed and to keep them safe. At The Valley Hospital, our cardiac clinical trials are for patients 18 years and older, but each one has its own restrictions and guidelines for enrollment. Participating in a clinical trial is voluntary.

WHAT HAPPENS DURING A CLINICAL TRIAL?

Clinical trials are carried out according to strict scientific and ethical principles. Patients receive treatment, and doctors carry out research on how the treatment affects the patients. You will receive your treatment at The Valley Hospital. Doctors, nurses, dietitians, technologists, and other healthcare professionals may be a part of your treatment team. They will follow your progress and schedule you for follow-up tests and monitoring at regular intervals.

WHAT RIGHTS DO I HAVE DURING A CLINICAL TRIAL?

Before, during, and after a trial you have certain rights. These include:

- Participation is up to you. You must be given all the facts about a study before you enroll. If you agree to take part in a study, you will be asked to sign an informed consent form.
- If you enroll in the study, doctors and nurses will follow your response to treatment carefully throughout the research.
- If researchers learn that a treatment harms you, you will be taken off the study right away. You may then receive other treatment from your doctor.
- You have the right to leave a study at any time.

WHAT QUESTIONS SHOULD I ASK MY DOCTOR AND/OR NURSE BEFORE ENROLLING?

Here are a few basic questions to consider. You may come up with many more:

- What is the purpose of the clinical trial?

- Why do researchers believe the experimental treatment being tested may be effective? Has it been tested before?
- How do the potential risks, side effects and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- What type of long-term follow-up care is part of this study?
- How will I know the treatment is working?
- Who will be in charge of my care?

HOW DO I ENROLL IN A CLINICAL TRIAL?

One of our research nurses will go over all of the information about the trial with you and/or someone you have advocated to make decisions for you if you are in an emergency situation and can't make the decision for yourself. You will be given an informed consent form to sign and will be instructed as to when your treatment will begin. Remember, you have the right to ask as many questions as you wish **before** you enroll and you may stop the trial **at any time**.

HOW CAN I FIND OUT MORE ABOUT CARDIAC CLINICAL TRIALS?

Ask your doctor or nurse any specific questions you have. For a listing of the trials open at The Valley Hospital, visit our web site at www.valleyhealth.com. Or you may call the Cardiac Clinical Trials office at 201-447-8453. We have specially educated registered nurses with vast experience in cardiac clinical trials who can answer your questions. The National Institutes of Health provides extensive information on clinical trials and can be reached by visiting www.clinicaltrials.gov.

Cardiac Clinical Trials is just one component of The Valley Hospital's commitment to providing the highest level of heart care available today. By testing new medications and treatment regimens, clinical trials help advance the standard of care. A clinical trial is one of the final stages of a long and careful research process that began with ideas in the laboratory.

You have been asked to take part in a clinical trial that is testing a new treatment for heart disease. This brochure provides you with information about clinical trials that will help you make your decision. Please do not hesitate to ask your nurse or doctor if there are any other concerns you have about the particular clinical trial that you are considering. They are the ones most familiar with your medical history and can help you to make the decision that is right for you. You may also want to discuss your decision with your spouse, children, other family members or friends. Remember, participating in a clinical trial is voluntary; it is your choice as to whether or not you will take part in a clinical trial.

AT THE FOREFRONT OF CARDIAC TREATMENT

The Valley Hospital's Cardiac Clinical Trials program is one component of Valley's comprehensive diagnostic, treatment, and management services for patients with all types of heart disease. Some of the many cardiology services at The Valley Hospital are cardiac surgery, cardiac catheterization, non-invasive diagnostic testing, echocardiograms, electrophysiology studies and cardiac rehabilitation. The physicians involved with cardiac care are board-certified and specialize in cardiac disease. To find a Valley Hospital cardiologist or cardiac surgeon, call 1-800-VALLEY 1 (1-800-825-5391) or visit www.valleyhealth.com.

The Valley Hospital thanks the National Institutes of Health for its educational materials about clinical trials.

Cardiac Clinical Trials

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CARDIAC CLINICAL TRIALS

AT THE VALLEY HOSPITAL

