UW Medicine
Cardiothoracic Surgery Division Clinical Trials
May 2009

Clinical Trials – Currently Enrolling Subjects:

HeartMate II	End-Stage Heart Failure
SCCOR IV	Open Heart Surgery Patients
INTERMACS	LVAD Patients
Relay	Thoracic Aortic Aneurysms
PARTNER	Aortic Valve Stenosis
Stem Cell Injection at LVAD Insertion	Advanced Heart Failure
RED-CABG	CABG
HeartWare LVAD	LVAD Patients
PleuraSeal	Open Thoracotomy Patients
IBV Valve Trial	Emphysema Patients
TAG 06-02	Thoracic Aortic 45mm Stent

HeartMate II

The Evaluation of the HeartMate II (HM II) Left Ventricular Assist Device Study

The purpose of this study is to determine the safety and effectiveness of the Thoratec HeartMate II Left Ventricular Assist System (LVAS) as Destination Therapy in end-stage heart failure patients who do not qualify for cardiac transplantation, and as a Bridge to Cardiac Transplantation in end-stage heart failure patients who are listed for cardiac transplant but are at imminent risk of dying.

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For more information, including inclusion/exclusion criteria, please click on the links below:
Destination Therapy:
http://clinicaltrials.gov/ct2/show/NCT00121485?term=heartmate+II&rank=2
Bridge to Cardiac Transplantation:

http://clinicaltrials.gov/ct2/show/NCT00121472?term=heartmate+II&rank=1

SCCOR IV

Immunomodulation Following Transfusion

A National Heart, Lung, and Blood Institute (NHLBI) sponsored, prospective clinical trial aimed at investigating the rate of allosensitization to blood transfusions and how leukoreduction (LR) and gamma irradiation (G) of blood products alter the recipients' immunoregulatory cells.

In this study, patients scheduled for cardiac surgery are randomly assigned to receive blood products pretreated in one of three ways: untreated, filtered or filtered and irradiated. If their physician orders transfusions, they will receive products assigned to their group. Patients are asked to provide two blood samples during the 4 weeks after surgery.

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For more information, including inclusion/exclusion criteria, click on the link below:
http://clinicaltrials.gov/ct2/show/NCT00810810

INTERMACS

Interagency Registry of Mechanically Assisted Circulatory Support

INTERMACS is a national registry for patients who receive an FDA approved durable mechanical circulatory support device to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives.

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For more information, including inclusion/exclusion criteria, please click on the link below:
http://clinicaltrials.gov/ct2/show/NCT00119834?term=intermacs&rank=1

RELAY

Phase II Study of the Safety and Efficacy of the Relay Thoracic Stent-Graft

The purpose of this study is to evaluate the safety and efficacy of the Relay Thoracic Stent-Graft System in the treatment of patients with thoracic aortic aneurysms. This stent-graft is designed to treat aortic aneurysms through endovascular surgery, an alternative to open surgical treatment. This is a multicenter, non-randomized, open label, active control, parallel assignment study.

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http://clinicaltrials.gov/ct2/show/NCT00435942?term=relay+thoracic&rank=1

PARTNER

Placement of Aortic Transcatheter Valves Trial

A prospective, randomized-controlled, multi-center pivotal trial to evaluate the safety and effectiveness of the Edwards SAPIEN Transcatheter Heart Valve in a stratified population of high risk patients. The purpose of this trial is to determine the safety and effectiveness of the device and delivery system in high risk, symptomatic patients with severe aortic stenosis.

Cohort A – High risk surgery patients undergoing transcatheter aortic valve implantation (treatment) vs. surgical aortic valve replacement (AVR) (control).

Cohort B – Non-surgical patients undergoing transcatheter aortic valve implantation (treatment) vs. best medical management (control).

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http://clinicaltrials.gov/ct2/show/NCT00530894?term=aortic+transcatheter+valve&rank=1

STEM CELL INJECTION AT LVAD INSERTION

Bone Marrow Stem Cells in Myocardium of LVAD Patients

The purpose of this study is to assess the efficacy of bone marrow derived stem cell populations on improving vascularization of ischemic myocardium. The study population will be patients with advanced heart failure resulting from ischemic heart disease requiring placement of an LVAD as a bridge to cardiac transplantation.

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RED-CABG

The Effect Of Acadesine On Reducing Cardiovascular and Cerebrovascular Adverse Events In Coronary Artery Bypass Graft (CABG) Surgery (RED-CABG)

The purpose of this study is to determine whether acadesine is effective in reducing the cardiovascular and cerebrovascular adverse events in high-risk patients undergoing CABG surgery.

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http://clinicaltrials.gov/ct2/show/NCT00872001?term=RED+CABG&rank=1

PLEURASEAL

Prospective Multicenter Randomized Clinical Study to Evaluate the PleuraSeal Sealant System as an Adjunct to Standard Closure Techniques for Control of Visceral Pleural Air Leaks Following Elective Pulmonary Resection Via Open Thoracotomy.

The purpose of this study is to evaluate the safety and effectiveness of the PleuraSeal Sealant System in the treatment and control of intra and postoperative air leaks following pulmonary resection via an open thoracotomy..

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http://clinicaltrials.gov/ct2/show/NCT00748124?term=pleuraseal&rank=2

IBV VALVE TRIAL

A Prospective, Randomized, Controlled Multicenter Clinical Trial to Evaluate the Safety and Effectiveness of the IBV Valve System for the Treatment of Severe Emphysema

The objective of this randomized, blinded, controlled trial is to demonstrate the ability of the IBV Valve System to be safely implanted in selected airways of human subjects with severe emphysema and to improve disease-related health status.

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For more information, including inclusion/exclusion criteria, please click on the links below:
http://clinicaltrials.gov/ct2/show/NCT00475007?term=IBV+Valve&rank=1

TAG 06-02

Evaluation of the GORE TAG® Thoracic Endoprosthesis – 45 mm for the Primary Treatment of Aneurysms of the Descending Thoracic Aorta

The study device is the GORE TAG® Thoracic Endoprothesis – 45 mm. The study device will be used to treat large aneurysms of the descending thoracic aorta. This research study will look at the safety and effectiveness of the study device.

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For more information, including inclusion/exclusion criteria, please click on the links below:
http://clinicaltrials.gov/ct2/show/NCT00590759?term=gore+tag&rank=1