

**UW Medicine
Division of Cardiology Clinical Trials
Revised 11-04-09**

Clinical Trials – Currently Enrolling Subjects:

PARTNER	Aortic Valve Stenosis
FREEDOM	Diabetes with multi-vessel CAD
RED-HF	Symptomatic LV systolic Dysfunction, anemia
PREMIUM	Headache reduction in migraine and PFO
TOPCAT	Congestive Heart Failure
BALANCE	Hyponatremia, Heart Failure
AIM-HIGH	Patients with atherogenic dyslipidemia, composite of CHD death, nonfatal MI, or ischemic stroke.

****** All studies are registered on clinicaltrials.gov for more information ******

PARTNER

Placement of Aortic Transcatheter Valves Trial

A prospective, continued access, multi-center pivotal trial evaluation 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

Cohort B – Non-surgical patients undergoing transcatheter aortic valve implantation

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For more information, including inclusion/exclusion criteria, please click on the link below:

<http://clinicaltrials.gov/ct2/show/NCT00530894?term=partner&rank=30>

FREEDOM

Future Revascularization evaluation in patients with diabetes mellitus: optimal management of multivessel disease.

FREEDOM is a multi-center, prospective, randomized clinical trial comparing coronary artery bypass surgery (CABG) with percutaneous coronary stenting using the Sirolimus-eluting stent in diabetic patients with multivessel disease. The main objective of the study is to compare a multivessel stenting strategy using Sirolimus-eluting stents with CABG with respect to mortality in 5 years of follow-up.

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For more information, including inclusion/exclusion criteria, please click on link below:
<http://clinicaltrials.gov/ct/gui/show/NCT00086450?order=4>

RED-HF

A Double-Blind, Randomized, Placebo-Controlled, Multi-center Study to Assess the Efficacy and Safety of Darbepoetin Alfa Treatment on Mortality and Morbidity in Heart Failure (HF) Subjects With Symptomatic Left Ventricular Systolic Dysfunction and Anemia

The purpose of the study is to determine the efficacy of treatment of anemia with darbepoetin alfa compared to placebo on the composite of time to death from any cause or first hospital admission for worsening HF in subjects with symptomatic left ventricular systolic dysfunction and anemia.

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For more information, including inclusion/exclusion criteria, please click on the link below:
<http://clinicaltrials.gov/ct/show/NCT00358215?order=1>

PREMIUM

Prospective Randomized investigation to Evaluate incidence of headache reduction in subjects with Migraine and PFO Using the AMPLATZER PFO Occluder compared to Medical Management.

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TOPCAT

Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist

This is a randomized, double-blinded, placebo-controlled trial of aldosterone antagonist therapy (15 mg dose spironolactone or placebo; titrated up to 45 mg/day) in 4,500 adult patients with heart failure and preserved systolic function. The purpose of this study is to evaluate the effectiveness of aldosterone antagonist therapy in reducing all cause mortality in patients who have heart failure with preserved systolic function.

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For more information, including inclusion/exclusion criteria, please click on the link below:

<http://clinicaltrials.gov/ct2/show/NCT00094302?term=topcat&rank=1>

BALANCE

Treatment of Hyponatremia based on lixivaptan in NHYA Class III/IV cardiac patient evaluation.

Patients who have congestive heart failure (CHF) often have problems of low sodium concentrations in their bodies from the CHF medications given to treat heart failure. The main purpose of this study is to find out if Lixivaptan can decrease the amount of extra water in the body in people with CHF who have low levels of salt in their blood. Other purposes of this study are to learn more about how Lixivaptan works to decrease the water and increase salt levels in the blood, and the timing of these effects, by collecting information from laboratory blood measurements at various times during treatment.

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For more information, including inclusion/exclusion criteria, please click on the link below:

<http://clinicaltrials.gov/ct2/show/NCT00578695?term=hyponatremia+based+on+lixivaptan+AND+class+iii+%2F+iv+cardiac+patient+evaluation&rank=1>

AIM-HIGH

AIM-HIGH is a multi-center, randomized, double-blind, parallel-group, controlled clinical trial designed to test whether the drug combination of extended release niacin plus simvastatin is superior to simvastatin alone, at comparable levels of on-treatment LDL-C, for delaying the time to a first major CV disease outcome over a 4-year median follow-up in patients with atherogenic dyslipidemia, composite of CHD death, nonfatal MI, or ischemic stroke.

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For more information, including inclusion/exclusion criteria, please click on the link below:

<http://clinicaltrials.gov/ct/gui/show/NCT00120289?order=1>