

Stem Cells for Chronic CHF post-MI

Patients with Chronic CHF, NYHA class II-IV, stable post-MI and on optimal medical therapy for >60 days and LVEF <35% at screening, will be randomized. Following randomization all subjects will receive a muscle biopsy to remove 10 grams of muscle tissue from the thigh or calf region. Subjects will receive percutaneous intramyocardial injections of autologous skeletal myoblasts or placebo. The goal of the trial is to improve symptoms and LVEF. Subjects will be randomized in a 1:1:1 ratio (low dose, high dose, placebo).

Dr. Gary Schaer (PI), 312.942.4655. Gary_Schaer@RUSH.edu
Christina Giannoulis (Study Coordinator), 312.942.9489

Gene Therapy for Critical Limb Ischemia



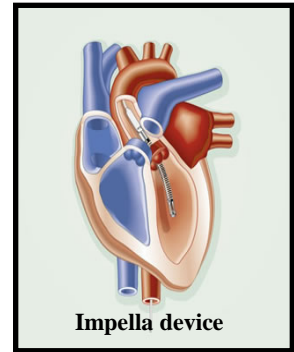
Patients diagnosed with Critical Limb Ischemia and skin lesions (either ulcer stable for 2-weeks or gangrene) will be randomized (1:1) to XRP0038/NV1FGF(gene product) or placebo administered by IM injections in leg. The study goal is to stimulate angiogenesis, reduce claudication and improve walking distance. Subjects with a history of cancer or have a planned leg amputation are excluded.

Dr. Jeff Snell (PI), 312.942.6569
Christina Giannoulis
(Study Coordinator), 312.942.9489

Circulatory Support for High Risk PCI

The Protect II trial will enroll non-emergent high risk patients undergoing PCI that may benefit from active circulatory support. The IMPELLA Recover LP 2.5 will be compared to IABP to determine if better hemodynamic support will reduce the rate of major adverse events for patients undergoing high risk PCI. Subjects will be randomized 1:1 and will be followed for a 3-month period.

Dr. Cliff Kavinsky (PI), 312.942.8771
Catherine Glase (Study Coordinator), 312.942.9398



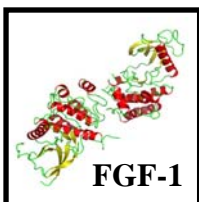
Impella device

Carotid Stenting



The ACT 1 trial will randomize (3:1) patients with significant carotid disease but no symptoms to carotid stenting (Xact stent and Emboshield distal protection) or surgical carotid endarterectomy. Study provides asymptomatic patients with preventative care against future strokes.

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Christina Giannoulis 312.942.9489



FGF-1

Angiogenic Growth Factor for Refractory Angina

Patients with severe angina refractory to medical therapy who are not candidates for CABG or PCI will be randomized to percutaneous intramyocardial injections using 3 doses of human recombinant fibroblast growth factor-1 (FGF-1) or placebo. The goal of this trial will be to evaluate safety and efficacy of FGF-1 injections to determine if angina frequency is reduced via myocardial angiogenesis. **Dr. Gary Schaer** (PI), 312.942.4655. Gary_Schaer@RUSH.edu