BEST - CLI TRIAL UPDATE

Michigan Vascular Study Group and BMC2
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Best Endovascular vs. Best Surgical Therapy in Patients with Critical Limb Ischemia

Sponsored by the National Heart Lung and Blood Institute
Chronic Limb Ischemia - CLI

- Pain at rest
  - Forefoot, leg/ calf
- Ulcers, gangrene
Critical Limb Ischemia (CLI) - Impact

- CLI is treated with measures to improve limb perfusion
- In the absence of revascularization, limb amputation rate in patients with CLI approaches 40%

Hirsch AT et al. J Am Coll Cardiol 2006;47:1239-1312
Trial Overview

- Prospective, randomized, multicenter, open label superiority trial
- **2,100** patients at **120** clinical sites in United States and Canada
- 4-year trial with each patient having minimum of 2 year follow-up
- Funded by National Heart Lung and Blood Institute at level of $24,990,000
Trial Overview

- Inclusion Criteria
  - Male or Female age 18 or older
  - Infrainguinal PAOD
  - CLI defined as arterial insufficiency with gangrene, ulceration or rest pain consistent with Rutherford categories 4-6
  - Candidate for both endovascular and open infrainguinal revascularization
  - Adequate aortoiliac inflow
  - Popliteal, tibial or pedal revascularization target which can support a distal anastomosis of a surgical bypass
  - Willingness to comply with protocol and follow up.
Trial Overview

• Exclusion Criteria
  – Popliteal aneurysm > 2cm in index limb
  – Life expectancy less than 2 years
  – Excessive risk for surgical bypass
  – Planned above-ankle amputation within 4 weeks of index procedure
  – Active vasculitis, Buerger’s disease, or acute limb-threatening disease
  – Any prior index limb infrainguinal stenting or stent grafting associated with significant restenosis within 1 cm of the stent or stent-graft, unless the occlusion/restenosis site is outside of the treatment zone
  – Any of the following procedures performed on the index limb within 3 months: pta, atherectomy, stent, bypass with either vein or prosthetic
Trial Overview

• Exclusion Criteria continued:
  – Open surgical inflow procedure within 6 weeks prior to enrollment
  – Current chemotherapy or radiation
  – Absolute contra-indication to iodinated contrast
  – Pregnancy or lactation
  – Administration of an investigational drug for PAOD within 30 days
  – Participation in a clinical trial within 30 days
  – Prior enrollment or randomization into BEST-CLI
Trial Objective

BEST Trial Aim

To compare **treatment efficacy**, **functional outcomes** and **cost** in patients with CLI and infrainguinal PAD undergoing best **open surgical** or best **endovascular** revascularization
Patient Population

Patients with CLI and infrainguinal PAD who are candidates for both open surgical infrainguinal revascularization and endovascular treatment, in the eyes of the individual investigator CLI team.
Map of BEST-CLI Sites
Enrollment Update

To date (9/14/17)
• First patient randomized 8/28/14
• 158 of 171 sites activated
• 1072 subjects randomized

Top 5 enrolling sites:
#1160 Keck Medical Center of USC - 52 subjects
#1258 Boston Medical Center - 50 subjects
#1238 Univ. of Massachusetts – 31 subjects
#1273 Univ. Florida (Gainesville) – 23 subjects
#1309 Iowa Heart – 22 subjects
Enrollment Goals

Milestones:
1,188 Subjects by 9/30/17
2,100 Subjects by 8/31/18
Top 10 Reasons for Screen Failures

- 909 = Excessive risk for surgical bypass
- 591 = Pt doesn’t want to be part of research
- 568 = Pt doesn’t want surgical procedure
- 523 = Inadequate aortoiliac inflow
- 509 = Disallowed index limb proc in prior 6mo
- 470 = Inadequate revascularization target
- 390 = Occlusive disease on imaging not severe enough
- 371 = Procedure performed on index limb within 3 months prior to enrollment
- 348 = Significant restenosis of prior stent/graft
- 316 = Other Reasons
Obstacles to enrollment

• Convincing partners to review and enroll their patients
• Introducing study to patients is difficult given that both open and endo are available as standard of care.
• Personal bias
• Lack of site specific plan for screening process and patient flow