

BEST-CLI – Race to the finish line with BEST!

April is showering us with more enrollments in BEST! BEST-CLI teams are kicking it into high gear this spring. Let's recruit more subjects to keep the study on track!

Pitching BEST-CLI to Eligible Patients: Shared Experience of Investigators on How to Present Participation in the Trial

From the Desktop of Alik Farber, MD

We are seven months into the trial and are critically evaluating obstacles to patient recruitment. Talking to patients about participating in BEST-CLI remains a challenge at some sites. We have discussed strategies with investigators at high enrolling sites in an effort to learn from their positive experiences in discussing the trial with prospective patients. Below are suggested key talking points to share with patients when discussing participation in the BEST-CLI trial:

- 1 There is a lot of variability in how CLI is treated in North America. *We currently don't know which treatment (surgery or endovascular therapy) is 'best' for your CLI.* The goal of this trial is to determine which therapy is best.
- 2 *Our goal is to save the affected leg by improving blood flow.* There are two treatment strategies (surgery and endovascular therapy) to increase blood flow. Both are standard of care. Both have specific benefits and risks.
- 3 Neither of the two treatment options, open surgery or endovascular therapy, are experimental, they are both *standard treatments* for CLI.
- 4 Our site is one of 120 sites across the US and Canada taking part in this *landmark trial* which is *supported by the National Institutes of Health.*
- 5 Your participation in this trial *could help your doctor, members of your own family,* should they develop CLI, or *even you* if you develop recurrent CLI or CLI in your other leg in the future.
- 6 While in this trial your care will be overseen by a *multidisciplinary group* consisting of vascular surgeons, interventional radiologists, interventional cardiologists, and research nurses/coordinators. (This may not be true for all sites, adjust as necessary for your site).

We hope that including these recommended talking points in your conversations with patients will help alleviate their concerns and bolster your confidence in recruiting for this trial. If you have any 'lessons learned' from your own site experience, please share them with us by emailing BEST@neriscience.com.

Protocol Eligibility Clarifications in BEST!

Based on site feedback, the Operations Committee met on March 11, 2015 to review and develop clarifications for several protocol exclusion criteria. Additional details are found in Ops Memo #4, posted to NERI Connect.

[Ops Memo #4](#)
[Click here](#)

Please keep a copy of this operations memo in your regulatory files for BEST-CLI.

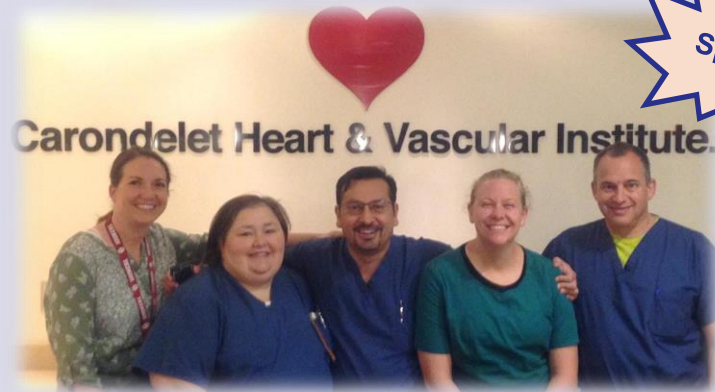
Request for Screening Logs!

Screening Logs are due bi-weekly to the DCC. The next round of screening logs is due

[May 1st](#)
[Click here](#)

Be sure to document all screen failures on your screening logs.

Carondelet Heart & Vascular Institute



From left to right: Shonda Banegas, DO, Rhonda Quick, MD, Bernardo Mendoza, MD, Emily Taylor, RN, Scott Berman, MD.

“The CLI team at Carondelet Heart and Vascular Institute has over 50 years of combined experience managing patients with severe lower extremity PAD. The group has adapted to the evolving care of the CLI patients over the past decade and have been leaders in the use of advanced limb salvage techniques in the Southwest including tibial and pedal bypass and free tissue transfer procedures from 2 decades ago to now advanced minimally invasive percutaneous revascularization procedures combined with novel wound healing adjuncts such as hyperbaric oxygen, negative pressure wound therapy and biologic wound dressings. The population of southern Arizona that the CHVI CLI team serves provides ample challenges including a significant incidence of diabetes and advanced renal disease in the native American and Hispanic populations endemic to the region. The team has an established reputation for success in clinical trials addressing lower extremity PAD and have been notable contributors to previous research efforts targeting this challenging population.”



Upcoming Investigator Meetings

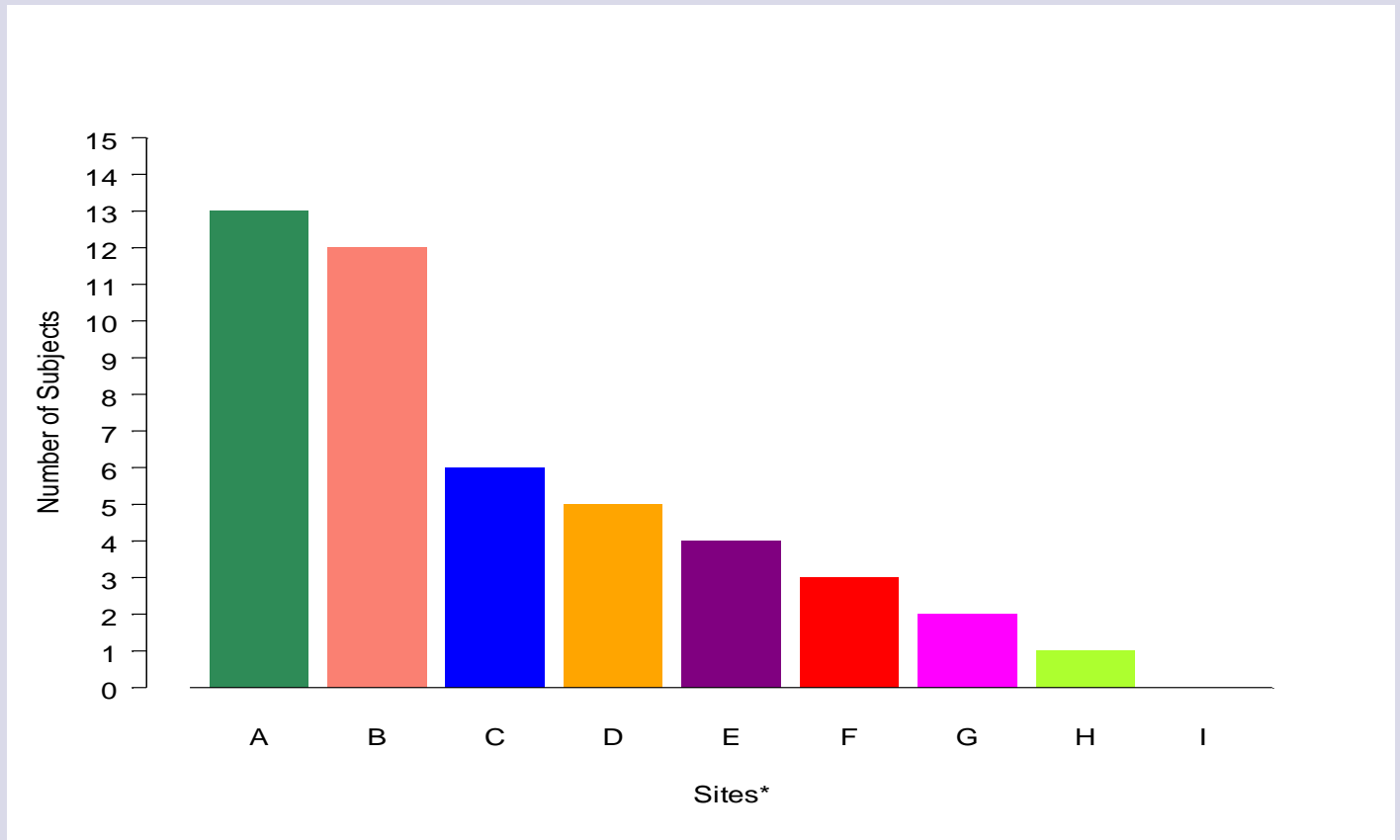


SCAI in San Diego, CA
 Thursday, May 7th from 7:00-7:45AM PT in the Aqua 303 Meeting Room, Hilton San Diego Bayfront



SVS in Chicago, IL
 Information Coming Soon!

Enrollment Leaderboard



Sites*

- A: 1258 – BMC
- B: 1160 - Keck MC of USC
- C: 1009 - Dartmouth Hitchcock MC
- D: 1108 - Michigan Heart/St Joseph Mercy Ann Arbor Hosp.; 1316 - Holy Name MC
- E: 1105 - Medical College of Wisconsin; 1281 - Western NY VA; 1282 - Carondelet Heart & Vascular Institute; 1288 - Kaiser Foundation Hosp.; 1309 - Mercy Hosp. MC
- F: 1005 - BWH; 1013 - Harbor-UCLA MC; 1055 - Mount Sinai MC; 1095 - Johns Hopkins Hosp.; 1260 - Greenville Memorial Hosp.; 1272 - St. Boniface General Hosp.; 1276 - Memorial Hermann Hosp. TMC
- G: 1041 - SFVAMC; 1046 - Steward St. Elizabeth's MC; 1076 - Northwestern Memorial Hosp.; 1113 - OHSU; 1169 – Univ. Hosp. of Cleveland; 1238 – UMass Medical School; 1269 - Ohio Health Research Institute; 1277 – Univ. of Utah; 1311 - Dallas VA MC; 1314 - Boston VA; 1318 – Univ. of NC Hosp.; 1331 - Pinnacle
- H: 1029 - Michael E. DeBakey VA MC ; 1030 - Montefiore MC; 1104 - Palo Alto VA; 1125 – UCSFMC; 1135 – Univ. of Pittsburgh MC; 1151 - William Beaumont Hosp. ; 1182 - Providence Heart and Vascular Institute; 1217 - UC Davis MC; 1256 - BIDMC; 1263 - Kaiser Permanente (San Diego); 1270 - Scott and White – Temple; 1271 – S. Illinois Univ. SOM; 1279 - North Carolina Heart and Vascular Research; 1290 - Loma Linda Univ. MC; 1294 - North Central Heart Institute; 1305 - Univ. of Virginia; 1308 - Ohio State Univ.; 1310 - Harborview MC; 1323 – Univ. of Nebraska MC; 1325 - Deborah Heart and Lung Ctr.
- I: 1003 - Allegheny General Hosp.; 1007 - Cleveland Clinic Foundation; 1010 - Emory Univ.; 1019 - Jewish General Hosp.; 1026 - Medstar Washington Hosp. Ctr.; 1034 - Ochsner MC; 1054 - Univ. of Colorado Hosp.; 1059 - Univ. of Alabama at Birmingham; 1061 - Baptist Hosp. of Miami; 1066 - Arizona Heart Hosp.; 1072 - Univ. of Wisconsin – Madison; 1075 - Swedish MC; 1101 - Albany MC; 1116 - Rush Univ. MC; 1123 - Thomas Jefferson Univ.; 1126 - Univ. of Chicago Medicine; 1134 - Univ. of Michigan Health System;

Enrollment Leaderboard Continued

Sites*

I: 1137 - The Univ. of Vermont MC; 1188 - Toronto General Hosp.; 1229 - Penn State Milton S. Hershey MC; 1234 - Univ. of Toledo MC; 1257 - Univ. of Arkansas for Medical Services; 1259 - Rhode Island Hosp.; 1261 - Indiana Univ. Medical School; 1264 - Minneapolis Heart Hosp.; 1274 - Univ. of Oklahoma Health Sciences Ctr.; 1275 - MUSC; 1280 - Metro Health Hosp.; 1287 - Providence Sacred Heart MC; 1289 - Lenox Hill Hosp.; 1293 - Univ. Health System: LSU Health Sciences; 1295 - Oklahoma Foundation for Cardiovascular Research; 1296 - Sacred Heart Hosp. River Bend; 1299 - Univ. of Tennessee MC; 1302 - UCLA-Gonda; 1304 - CAMC Clinical Trials Ctr.; 1315 - George Washington Univ. Hosp.; 1317 - Roper Hosp.; 1319 - Hunterdon MC; 1320 - Portland VA MC; 1326 - Miriam Hosp.-Brown Medical School; 1327 - Wellmont Holston Valley MC; 1330 - The Heart Center of Lake County; 1332 - Denver VA MC; 1336 - Staten Island Univ. Hosp.

*Site names abbreviated to accommodate space.

Frequently Asked Question:

Q: Do I have to report all of the outpatient procedures or tests that my subject has?

A: Only the procedures and tests specifically outlined on the Additional Procedure/Diagnostic Test page in eCOS need to be reported for the study as listed below:

- Dialysis
- Tracheostomy
- Gastrointestinal endoscopy
- Cardiac Catheterization
- CT scan (including angiography)
- MRI (including angiography)
- Ultrasound (including venous or arterial ultrasound studies)
- Echocardiogram
- Cardiac stress test
- Physical therapy

If any of these procedures or tests occurred during an inpatient hospitalization, they will be reported on the Hospitalization/ED Encounter page instead.

If the subject had other outpatient procedures not listed above, the outpatient visit may still be counted on the Healthcare Utilization page (question B4a).

If you have any data management or eCOS-related questions at your center please send an email to BEST-DM@neriscience.com.