BEST-CLI – Be At Your BEST This Winter!

Warm up your month with more enrollments in BEST! Despite the cold weather for many BEST-CLI teams, now is the time to crank up the heat on recruitment efforts! We need at least 1 subject per site per month to reach 2100 subjects by August 31, 2016. Let's do it!

From the Desktop of Alik Farber, MD

Vincent Rowe (VR) and Leonardo Clavijo (LC) and Specialty Principal Investigators at the Keck Medical Center of the University of Southern California (USC), have enrolled the most patients into BEST-CLI in the shortest period of time. I caught up with them last week to find out about how they achieved their success.

What is the process of screening patients at your site?

VR: At USC, all patients with critical limb ischemia (CLI) are seen by an integrated vascular team of physicians including vascular surgeons, vascular medicine doctors and interventional cardiologists. This program has been in place for five years. With the initiation of enrollment for the BEST-CLI trial we decided to halt all ad-hoc interventions in CLI and consider all CLI patients as potential candidates for the trial. We evaluate the patient, perform a lower extremity non-invasive laboratory series that includes toe pressures, decide if revascularization is necessary and if so, perform both vein mapping and a diagnostic lower extremity angiogram. We then review all clinical information at our weekly preoperative conference as a group and at that time we decide whether a given patient is a candidate for BEST-CLI.

How do you approach patients considered for BEST-CLI and how do you discuss trial participation with them?

LC: We consider all CLI patients with low toe pressures to be potential candidates for the BEST-CLI trial. Once our group has decided that the patient is a potential candidate for the study we approach the patient. Usually a surgeon and an interventional cardiologist, together, participate in this interaction. We discuss potential participation in the study with the patient and family. We inform patients that despite our extensive experience with CLI, at this time, the best revascularization strategy for patients with CLI is not known and that both surgical bypass and endovascular options are available. We provide detailed information about each procedure. We then discuss with the patient and family the need for additional information and testing, and the follow-up schedule necessary for the study. We assure them that although we cannot completely guarantee a successful outcome, our goal with either type of treatment is for them not to lose their leg.

How have you implemented and operationalized the concept of the "BEST-CLI team" at your site?

VR: As mentioned before, at USC we have been working together for the last five years as an integrated vascular team. For the BEST-CLI study we made some minor changes to our initial evaluation protocol and consider all CLI patients potential candidates for the study.

What has been your biggest obstacle to enrollment? How have you been able to overcome this obstacle?

LC: Perhaps the biggest obstacle for enrollment in the study is the socio-economic condition of some of our CLI patients. We spend a lot of time talking to patients and families to identify those who we think will be able to comply with medical treatment, wound care and follow-up.

What advice do you have for other sites that are struggling to enroll patients?

VR: Working as a team is essential. One has to consider all CLI patients as potential candidates for the study. Lastly, one should avoid jumping into performing an endovascular procedure for these patients before they are screened and fully considered for possible enrollment.

How have the investigators on your CLI team been able to put their own biases aside to consider patients to be eligible for both open surgery and endovascular therapy?

LC: This has been, perhaps, the most difficult part of the study. All of us have preconceived notions, anecdotal experience and biases on how to treat CLI patients. Many times we are simply unaware of all available endovascular or surgical options. For us, the strategy of getting all diagnostic tests and then reviewing them as a group to decide if the patient is a candidate for the BEST-CLI trial helps us to put aside our personal biases.

Funded by: NIH National Heart, Lung, and Blood Institute

Keck Medical Center of the University of Southern California (USC)
Congratulations on being the top enrolling site this month!

From left to right: Vincent Rowe and Leonardo Clavijo

Site Spotlight

Calling all Screen Failures!

The next round of screening logs is due to the DCC by March 6th!

Make sure all screen failure information is documented on your screening logs before submitting to the DCC.

BEST January Highlights

Number of New Sites Activated: 13

Top Enroller: 1160 Keck Medical Center of USC

Sites Enrolling 1st Subject: 6

DSMB Memo on NERI Connect!

The BEST-CLI DSMB completed its first meeting on Tuesday, January 27, 2015. A DSMB memo, which was a result from the first meeting, has been posted to NERI Connect.

Click here

Please follow your institutional guidelines when it comes to notifying your IRBs of this information.

Frequently Asked Questions:

Q: How can I enter a Dose Area Product (DAP) result on the Endovascular Procedure Details eCRF that fits within the expected range in eCOS?

A: You may need to convert the units of the DAP result for the system to accept the value. You may use the total or cumulative Kerma result for the conversion using the formulas in the table below:

Table 1
Kerma-area-product Unit Conversion

Unit Used	To Convert to Gy · cm^2
dGy · cm^2	divide by 10
cGy · cm^2	divide by 100
mGy · cm^2	divide by 1,000
μGy · m^2	divide by 100

Q: Can we add an investigator to the BEST-CLI Study?

A: Yes, to add an investigator, please complete the following:

- Send the DCC the investigator's CV, financial disclosure form and medical license
- Add the investigator to the Statement of Investigator and Delegation log and send these to the DCC
- Have the investigator complete training and add the investigator to the site training log
- Send the DCC the Site Staff ID form posted to NERI Connect in order to add them to the SIMC list for credentialing
- Send the investigator's completed attestation form to the DCC

Investigators not credentialed and/or trained are not allowed to perform any study procedures until completed

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Enrollment Leaderboard*

Site # / Name	# Rand
1258 / Boston Medical Center	7
1160 / Keck Medical Center of USC	6
1105 / Medical College of Wisconsin	4
1108 / Michigan Heart/St Joseph Mercy Ann Arbor Hospital	4
1316 / Holy Name Medical Center	4
1260 / Greenville Memorial Hospital	3
1281 / VA Western NY Healthcare System	3
1005 / Brigham and Women's Hospital	2
1009 / Dartmouth Hitchcock Medical Center	2
1013 / Harbor-UCLA Medical Center	2
1055 / Mount Sinai Medical Center	2
1095 / Johns Hopkins Hospital	2
1277 / The University of Utah	2
1282 / Carondelet Heart & Vascular Institute	2
1311 / Dallas VA Medical Center	2
1331 / Pinnacle Health System	2
1029 / Michael E. DeBakey VA Med Ctr.	1
1030 / Montefiore Medical Center	1
1041 / San Francisco Veterans Affairs Medical Center (SFVAMC)	1
1046 / Steward St. Elizabeth's Medical Center	1
1104 / VA Palo Alto	1
1151 / William Beaumont Hospital affiliated Beamont Health System	1
1182 / Providence Heart and Vascular Institute	1
1238 / University of Massachusetts Medical School	1
1256 / Beth Israel Deaconess Medical Center	1
1263 / Kaiser Permanente (San Diego)	1
1269 / Ohio Health Research Institute	1
1272 / St. Boniface General Hospital	1
1288 / Kaiser Foundation Hospital	1
1310 / Harborview Medical Center	1
1318 / University of North Carolina Hospitals (Chapel Hill)	1
1323 / University of Nebraska Medical Center	1
Total	**65**

*Full site listing available on NERI Connect

Not activated yet? Here are four easy steps to get there:

- Submit your IRB approval memo to the DCC
- Execute the Clinical Trial Agreement
- Attend BEST-CLI training webinar
- Submit required regulatory documents to the DCC

Contact your CRA for more information and to find out how to activate your site for enrollment.