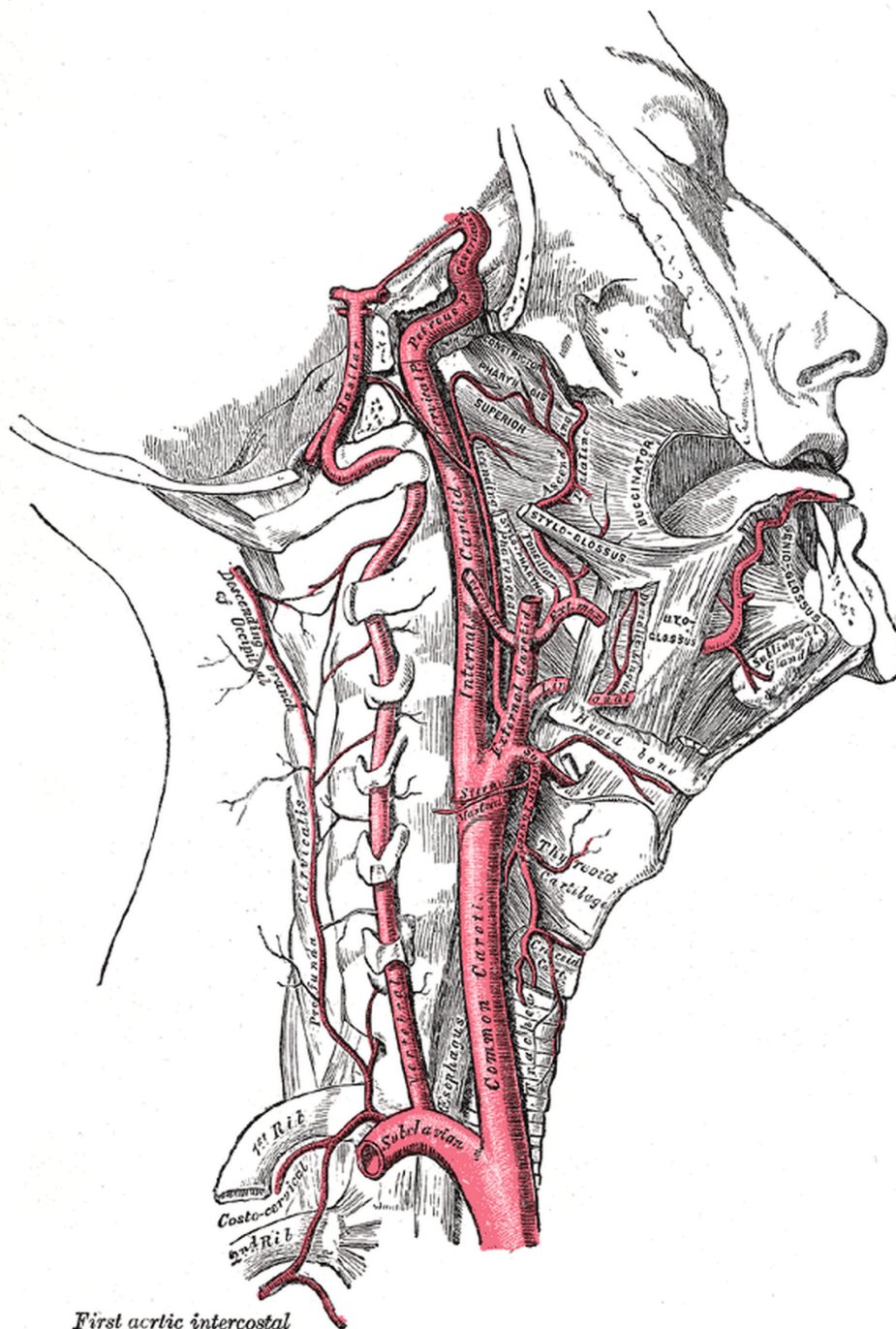


PRaCTUS BCVI

Pragmatic Randomized Clinical Trial of Universal Screening for Blunt Cerebrovascular Injury
Now inviting Level 1 and Level 2 trauma centers to participate



First aortic intercostal

Illustration: H.V. Carter, Gray's Anatomy of the Human Body, 20th ed. (1918), Fig. 513. Public domain.

Funded by an AAST Multi-Institutional Trials Committee Sprint Grant
Coordinating Center: Inova Fairfax Medical Campus, Falls Church, VA
Stefan W. Leichtle, MD, MBA, FACS | Stefan.Lleichtle@inova.org | 703-776-4518

PRaCTUS BCVI

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We are seeking five Level 1 or Level 2 trauma centers that currently use selective BCVI screening and are considering a move to universal screening. Participation means making that change on a randomized schedule and reporting data largely drawn from your trauma registry.

Why this trial

BCVI occurs in 3% to nearly 8% of major blunt trauma patients, is usually silent at presentation, and carries reported stroke and mortality rates of 7% and 12%. Antithrombotic therapy started before symptom onset substantially reduces this risk, and most strokes occur within 72 hours. Even the most extensive screening criteria may miss up to one third of injuries. Universal screening with CTA neck detects more BCVI, but whether this prevents strokes and deaths has never been tested prospectively. Both strategies are endorsed by current guidelines, and practice varies widely. After more than two decades of retrospective studies, this will be the first prospective, randomized comparison of BCVI screening strategies.

Study at a glance

Design	Pragmatic stepped-wedge cluster-randomized trial; the trauma center, not the patient, is the unit of randomization
Sites	Five ACS-verified and/or state-designated Level 1 or 2 trauma centers currently using selective screening
Population	Adult (18 years and older) major blunt trauma patients, defined as those undergoing whole-body trauma CT or at minimum CT cervical spine and/or CTA chest
Comparison	Selective screening using your center's existing criteria (control) versus CTA neck for all major blunt trauma activations (intervention)
Treatment	Not standardized. Management of detected BCVI remains at clinician discretion per your institutional practice
Primary outcome	BCVI-related ischemic stroke per 1,000 major blunt trauma admissions
Other outcomes	BCVI-related stroke or stroke-related death; antithrombotic-related bleeding; acute kidney injury; BCVI detection rate and grade; CTA utilization
Duration	12 months of data collection, with an interim analysis at month 4 for the 2027 AAST Annual Meeting

Crossover schedule

All centers begin with selective screening (SS). Every two months, one randomly assigned center crosses over to universal screening (US) and remains there. The sequence is randomized before study start, so each center knows its crossover date in advance and can prepare. No center stays in the control condition, and each serves partly as its own control.

	Mo 1-2	Mo 3-4	Mo 5-6	Mo 7-8	Mo 9-10	Mo 11-12
Center A	SS	US	US	US	US	US
Center B	SS	SS	US	US	US	US
Center C	SS	SS	SS	US	US	US
Center D	SS	SS	SS	SS	US	US
Center E	SS	SS	SS	SS	SS	US

Who can participate

- ACS-verified and/or state-designated Level 1 or Level 2 trauma center currently using selective screening for BCVI
- Willingness to adopt universal screening on the randomized schedule, with written permission from the Trauma Medical Director
- Site PI who is a board-certified surgeon with active trauma privileges
- Staff available to extract registry data, complete chart review for BCVI and stroke cases, and join study calls

What participation involves

When	What your site does
Before study start	Obtain local IRB approval (the coordinating center recommends a waiver of consent and HIPAA authorization); execute the Data Use Agreement; Trauma Medical Director signs a letter of organizational permission; site personnel complete study-specific training; complete Form 1 (center questionnaire and current screening criteria)
At your crossover	Trauma Medical Director releases the updated protocol: CTA neck for all major blunt trauma activations from the assigned date onward
Every 2 months	Form 2: aggregate counts for major blunt trauma patients (CTA neck performed, BCVI by grade, ischemic strokes, stroke-related deaths, AKI), drawn from your trauma registry
Rolling	Form 3: one short form per patient with confirmed BCVI or ischemic stroke, entered within 30 days of discharge or death; the only component requiring chart review
Throughout	Kickoff call, quarterly updates, and prompt reporting of protocol deviations to the coordinating center and your IRB

Expected workload. Form 2 is submitted six times over the study. Based on published rates, we anticipate 30 to 80 BCVI cases and 3 to 5 BCVI-related strokes per center per year, which determines the number of Form 3 entries. Most variables are already part of the National Trauma Data Standard.

What the coordinating center provides

Inova Fairfax Medical Campus serves as the clinical and data coordinating center. We provide the protocol and all amendments, a secure REDCap database in which each site sees only its own data, a standardized data dictionary, study-specific training, randomization, data quality reports, and direct access to the study PI. Interim and final results are shared with all site PIs before publication.

Financial support. Funding for this pilot is limited, but each participating site receives \$1,000 toward local IRB application costs and \$200 per year for materials, to offset part of the site's costs.

Regulatory and ethics

The trial follows the Ottawa Statement on cluster randomized trials and is classified as research. Both strategies are guideline-endorsed standard of care and the study does not alter treatment once BCVI is diagnosed, so incremental risk is minimal. Each site obtains approval through its local IRB. Only de-identified data are transmitted to the coordinating center under a Data Use Agreement. The trial is in the process of being registered with ClinicalTrials.gov, which will be completed before the first site is activated.

Looking ahead

This pilot tests site recruitment, consistency of outcome definitions, event rates, and adherence after crossover. It lays the groundwork for a definitive, adequately powered trial of at least 20 trauma centers over three or more years. Pilot sites will be well positioned to continue into that trial.

Interested? Contact us

Stefan W. Leichtle, MD, MBA, FACS, Study Principal Investigator, Inova Fairfax Medical Campus, Falls Church, VA | Stefan.Lleichtle@inova.org

Surgery Research Team, Inova Fairfax Medical Campus, Falls Church, VA | surgery.research@inova.org