



Prairie

EDUCATION & RESEARCH COOPERATIVE

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CHOICE

Trial Sponsor: Abbott Vascular

Principal Investigator: Gregory J. Mishkel, MD

Trial Name: Carotid Stenting For High Surgical-Risk Patients; Evaluating Outcomes Through The Collection Of Clinical Evidence

Purpose: The purpose of this study is to 1) Provide additional information that the commercially available Abbott Vascular Carotid Stent Systems and Embolic Protection Systems can be used successfully by a wide range of physicians under commercial use conditions. 2) Provide an ongoing post-market surveillance mechanism for documentation of clinical outcomes and for possible extension of the Centers for Medicare and Medicaid Services (CMS) coverage to a broader group of patients.

Details: The CHOICE study will provide a mechanism for collection of data from Abbott Vascular's Carotid Stent Systems and Embolic Protection Systems when used by a broad group of physicians under commercial use conditions. The original CAPTURE and EXACT studies had built-in features that limited the ability to collect on-going real world data because they restricted the number of sites that could participate (up to 150 sites) and limited enrollment at each site (up to 50 patients per site). This study will not have these restrictions. The CHOICE study will also provide an ongoing post-market surveillance mechanism for documentation of clinical outcomes and for possible extension of the Centers for Medicare and Medicaid Services (CMS) coverage to a broader group of patients.

Eligibility

Genders Eligible for Study: Both

Inclusion Criteria:

- Patient or patient's legally authorized representative provided informed consent.
- Patient is considered at high risk for carotid endarterectomy (CEA).
- Patient requires percutaneous carotid angioplasty and stenting for carotid artery disease.
- Patient's physician intends to use an RX Acculink with the RX Accunet in the carotid artery or an Xact with the Emboshield in the carotid artery as per the FDA approved Indications for Use as outlined.