

Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis

*Please see full protocol for entire listing of inclusion/exclusion criteria.

<u>**Design:**</u> Two parallel, randomized clinical trials to assess in asymptomatic patients with ≥ 70% carotid stenosis:

- Outcome differences between medical management and carotid endarterectomy (CEA).
- Outcome differences between medical management and carotid artery stenting (CAS).

*Selected General Inclusion Criteria:

- ≥ 70% extracranial carotid stenosis by catheter angiography or ≥ 70% by duplex ultrasound defined by a peak systolic velocity (PSV) of at least 230 cm/s AND at least ONE of the following:
 - a. end diastolic velocity ≥ 100 cm/s, or
 b. internal carotid/common carotid artery
 PSV ratio ≥ 4.0, or
 - c. \geq 70% stenosis by CTA, **or**
 - d. \geq 70% stenosis by MRA.
- No ipsilateral stroke or TIA ≤ 180 days of randomization.

*Selected General Exclusion Criteria:

- Prior major ipsilateral stroke, mRS ≥ 2 .
- Chronic or paroxysmal atrial fibrillation requiring anticoagulatoin.

*Selected Specific CEA Exclusion Criteria:

- Reaction to anesthesia not overcome by pre-medication.
- Distal/intracranial stenosis > index lesion.

*Selected Specific CAS Exclusion Criteria:

- Type III, aortic arch anatomy.
- Angulation or tortuosity (≥ 90 degree) of the innominate and common carotid artery.
- Severe angulation or tortuosity of the internal carotid artery that precludes safe deployment of embolic protection device or stent.
- Non-contiguous lesions and long lesions (>3 cm).

For more information call 844-956-1826.

www.crest2trial.org

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