

# *ACE Pocket Protocol*

## ASA and Carotid Endarterectomy

**RESEARCH QUESTION:** Is the risk of stroke and death following carotid endarterectomy, influenced by the prescription of high vs. low doses of ASA, started prior to surgery and continued for 3 months.

**RESEARCH DESIGN:** Randomized, triple blind clinical trial.

**RECRUITMENT GOAL:** 2800 patients, 700 per treatment group.

**TREATMENTS:** Patients are randomly assigned to an ASA regimen of: **81 mg./day**, **325 mg./day**, **650 mg./day**, or **1300 mg./day**. All tablets are enteric coated and come in identical appearing blister pacs.

**ELIGIBILITY:** Patients scheduled for carotid endarterectomy by a NASCET or other approved surgeon are eligible (regardless of degree of stenosis and whether or not they have symptoms) provided:

- ❶ Patient is not participating in NASCET or another trial.
- ❷ No CABG surgery in past 30 days, nor scheduled in next 30 days.
- ❸ Patient can tolerate 1300 mg. of ASA per day for 3 months.
- ❹ Patient will not receive ASA from other sources during the trial.
- ❺ Patient will not take other antiplatelet drugs during the trial.
- ❻ If patient has taken  $\geq 325$  mg. of ASA in either of the past 2 days surgery must be scheduled  $\geq 48$  hrs since last dose was taken.
- ❼ If surgery is scheduled in next 24 hrs patient must be able to take first days dose of study medication at least 8 hrs before surgery.
- ❽ Patient has provided informed consent.

### ASSESSMENTS:

- Entry** (1 page) > Eligibility and Registration Form.  
**Baseline** (8 pages) > History, Examination and Test Results.  
**Surgery** (1 page) > Surgical Report Form.  
**Discharge** (3 pages) > Complications and Patient Status.  
**1 Month** (3 pages) > Patient Status.  
**3 Month** (6 pages) > Patient Status and Compliance.

### EVENT REPORTS:

- Stroke** (4 pages) > Location, Symptoms, Exam, Test Results.  
**Death** (1 page) > Cause of Death.  
**M.I.** (1 page) > Symptoms, ECG, Enzymes, Outcome.

Research Team: NASCET Collaborators.

Funded by: N.I.N.D.S.

# A C E

## PRACTICAL PROCEDURES

**STUDY KITS:** Contain supplies for 12 patients including:

- > 12 sequentially numbered patient medication boxes, each containing 13 one week blister pacs of study drug (ASA).
- > 12 sets of sequentially numbered case report forms (CRFs).

**RANDOMIZATION:**

- ❶ Check patient eligibility criteria (see over).
- ❷ Assign next sequential Patient ID number and get pre-numbered folder of data forms and medication box from current study kit.
- ❸ Complete the one page patient entry form (Form 1.0).
- ❹ Dispense one of the 13 blister pacs from the medication box. Print Patient ID number, name and medication start date on the cover.
- ❺ Provide patient with "Patient Info Card" and review instructions.
- ❻ Fax the one page patient entry form (Form 1.0) the same day
- ❼ Complete and fax the 8 page baseline form before surgery.

**STUDY MEDICATION:** Dispense blister pacs as needed in hospital, on discharge, and at 1 month follow-up visit. Check and encourage patient compliance. Collect used blister pacs to record compliance.

**DATAFAX:** (905) 574-4755.

- ❶ Fax completed CRFs ASAP after each patient assessment.
- ❷ CRFs will be reviewed within 24 hrs at the coordinating center.
- ❸ Any problems will be flagged with a brief quality control note.
- ❹ A quality control report will be faxed to each center weekly.
- ❺ Please respond by correcting and re-faxing CRFs as needed.

**SITE MONITORING:** A random sample of participating centers will be visited during the trial to validate study data against medical records, and to check drug supplies.

**ENDPOINT REVIEW:** All event reports (strokes, deaths and M.I.s) will be reviewed by a central endpoint adjudication committee.

**QUESTIONS?** Call the ACE Coordinating Center (905) 521-2100 ext 4093