

DRAFT PATIENT CONSENT FORM

Study Name: ASA and Carotid Endarterectomy (ACE)
A Randomized Trial Of 4 Doses of ASA For The Prevention Of Peri-operative Stroke In Carotid Endarterectomy

Investigators: NASCET Collaborative Study Group
consisting of surgeons, neurologists, neuroradiologists, epidemiologists and biostatisticians from 80 academic institutions in the USA and Canada

Granting Agency: National Institute of Neurological Disorders and Stroke (NINDS)

I have been asked to participate in this clinical research study because I am scheduled for surgery, specifically carotid endarterectomy, an operation to prevent stroke. There are however serious risks associated with this operation, namely stroke and death, which occur in about 5 percent of patients receiving this operation in North America.

The purpose of this study is to compare 4 doses of ASA (aspirin) for their ability to reduce the risk of stroke and death from the operation, during the 3 month period immediately following surgery. All patients who participate in this study will receive ASA; no one will receive a placebo. The 4 doses under study are 80mg, 325mg, 650mg and 1300mg. In terms of the standard, regular strength, ASA tablets this is equivalent to 1/4, 1, 2, or 4 tablets per day. All tablets will be enteric coated to reduce the chance of stomach upset, which sometimes occurs with ASA. These side effects of ASA include bleeding, heartburn, gastritis, and dyspepsia. Other side effects may include tinnitus, nausea and vomiting.

I understand that there is an equal chance that I will receive one of the 4 ASA doses, which will be provided in identically appearing blister packs, with 5 tablets to be taken each day (3 in the morning and 2 in the evening, with meals). Neither I nor my physicians will know which dose I have been given, but should my doctor need to know, this information will be made available.

As a patient enrolled in this study I will continue to receive medical care and while I may benefit from the increased medical supervision for this study, no benefit from the study drug can be guaranteed. This study will provide important information regarding the relative efficacy and safety of the 4 ASA doses regimens for patients undergoing carotid endarterectomy. Many patients including myself may benefit from this information.

I understand that it is important that I take the study drug each day and avoid all other sources of ASA for the 3 months of my participation in this study. While I must avoid over-the-counter products which contain ASA, I will be able to use acetaminophen for minor aches and pains, if necessary. I will check with my doctor before starting any new medicines during the study. Essential medications which I require for other medical conditions are allowed.

Following discharge from hospital after the operation I will be asked to return for follow-up

assessments at 30 days and 3 months after the operation, and will be asked to bring my study medication pacs with me. The study drug will be provided free of cost and there will be no additional medical tests or treatments required for the study beyond those required by my physicians for my operation and subsequent medical care. In the event of any medical or surgical complication I will be provided with appropriate medical treatment. However, neither free medical care nor any financial compensation for illness or injury will be provided.

All data collected for the study will be held in confidence and only used to answer the research questions posed by the investigators. I will not be identified individually in any listing or report arising from this study. When the trial is completed (approximately July 1997) I will receive a personal letter from the study investigators which will include a short description of the study findings.

I understand that my participation in this study is voluntary, that my refusal to participate will involve no penalty, compromise my medical care, or lead to loss of any benefits to which I am otherwise entitled, and that I may discontinue my participation in the study at any time without penalty or loss of benefits. I further understand that my doctor or the study investigators may decide to discontinue the study drug at any time for medical reasons or if it is in my best interest to do so. Further, any new findings which may arise during the course of this research which may relate to my willingness to continue will be provided to me.

All of my questions have been answered and I voluntarily consent to participate in this research study. If I have any further questions about this study I may contact the study coordinator or participating clinical investigator in my center listed below.

Study Coordinator _____ Telephone _____

Clinical Investigator _____ Telephone _____

I will be given a copy of this signed consent form which I have read and understood.

Print Patient's Name Patient's Signature Date

Print Name of Witness Witness Signature Date