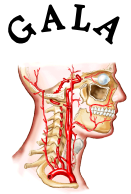

GALA

General Anaesthesia vs Local Anaesthesia for Carotid Endarterectomy

Protocol Summary

Background: severe stenosis of the carotid artery is often treated by carotid endarterectomy. Although trials have confirmed the benefit of this procedure, it is not without risks. Meta-analysis indicates that local rather than general anaesthesia for carotid endarterectomy may give a 40% reduction in the relative odds of peri-operative stroke or death. However, since most of the data are from non-randomised studies, a large randomised controlled trial is required to determine whether the method of anaesthesia influences peri-operative mortality and morbidity, and long term stroke-free survival.

Trial design: multicentre randomised trial conducted mainly in Europe. A central randomisation service, along with data management and analysis, is provided from the Trials Office in Edinburgh. Allocation uses balanced blocks with variable block size, stratified for centre. The trial is managed by a Steering Committee and the interests of the randomised patients protected by an independent Data Monitoring Committee.

Eligibility: in the opinion of the responsible clinician, any patient requiring an endarterectomy who is suitable for either local or general anaesthesia, and there is no clear indication for either type. Patients with either symptomatic or asymptomatic stenosis for whom surgery is advised are eligible. There is no upper age limit.

Exclusions:

- Failure to obtain fully informed consent
- Patient unable to co-operate with awake testing during local anaesthesia
- Patient considered unsuitable for general anaesthesia
- Patient considered unsuitable for local anaesthesia
- Patient requires simultaneous bilateral carotid endarterectomies
- Carotid endarterectomy combined with another operative procedure
- Patient has been randomised into the trial previously

Follow-up: data will be collected at discharge, or 7 days post-surgery or death, whichever is soonest. One month follow-up post-surgery will be by an independent stroke physician or neurologist. At one month post-surgery all surviving UK patients will also be sent a health related quality of life questionnaire for self-completion and postal return (non-UK patients will not be sent this questionnaire). A further patient questionnaire will be sent one year after surgery, and annually thereafter. Patients' family doctors will be contacted prior to annual follow-up to make sure that the patient is still alive. The severity of all non-fatal strokes will be determined by the modified Rankin scale.

Outcomes: the primary outcome is the proportion of patients alive, stroke free (including retinal infarction) and without myocardial infarction (MI) 30 days post-surgery. Secondary outcomes include proportion alive and stroke free at one year and in the longer term, a comparison of health related quality of life at 30 days and any surgical adverse events, re-operation and re-admission rates, the relative cost of the two methods of anaesthesia, length of stay and intensive and high dependency bed occupancy.

Statistical analyses: all analyses will be by intention-to-treat and compare all patients allocated to general anaesthesia versus all those allocated to local anaesthesia. The sample size will be 5000 patients.

Data ownership and publication: all data are owned by the collaborators to analyse and publish as the Steering Committee sees fit, without any influence of the trial sponsors (the PPP Foundation).