

GALA GENERAL ANAESTHESIA vs LOCAL ANAESTHESIA FOR CAROTID SURGERY RANDOMISATION NOTEPAD

Patients are eligible if:

- require carotid endarterectomy for either symptomatic or asymptomatic carotid stenosis
- clinician is uncertain whether to recommend general or local anaesthetic
- unilateral carotid endarterectomy is the only operation being done
- have given his or her informed consent to randomisation

Patients are not eligible if:

- clinician is certain about whether to recommend local or general anaesthetic
- require bilateral simultaneous endarterectomy
- patient has previously been randomised in this trial
- unable to co-operate with awake testing

HOSPITAL CODE NUMBER: or Hospital name

PATIENT DETAILS:

Family name:

First names: Hospital number

Date of birth: dd / mm / yyyy Male Female

Patient has given informed consent? YES (MUST be answered 'Yes' before patient can be randomised)
 Patient able to co-operate with awake testing? YES (MUST be answered 'Yes' before patient can be randomised)

DATE FOR OPERATION (dd/mm/yyyy) / / Actual date / Estimated date (delete as appropriate)

NAME OF RANDOMISING DOCTOR PLEASE PRINT CLEARLY

TODAY'S DATE (dd/mm/yyyy) / /

CEREBROVASCULAR EVENTS AT ANY PREVIOUS TIME

Please tick either Yes or No for each question and enter all relevant dates and numbers of events

	YES	NO	IF YES:	Date (dd/mm/yy) of most recent event
1. Hemispheric stroke (carotid distribution)	<input type="checkbox"/>	<input type="checkbox"/>	→ Right brain Left brain	<input type="text"/> <input type="text"/>
2. Hemispheric TIA (carotid distribution)	<input type="checkbox"/>	<input type="checkbox"/>	→ Right brain Left brain	<input type="text"/> <input type="text"/>
3. Vertebrobasilar stroke	<input type="checkbox"/>	<input type="checkbox"/>	→ IF YES:	<input type="text"/>
4. Vertebrobasilar TIA	<input type="checkbox"/>	<input type="checkbox"/>	→ IF YES:	<input type="text"/>
5. Retinal infarct	<input type="checkbox"/>	<input type="checkbox"/>	→ Right eye Left eye	<input type="text"/> <input type="text"/>
6. Amaurosis fugax (transient monocular visual loss)	<input type="checkbox"/>	<input type="checkbox"/>	→ Right eye Left eye	<input type="text"/> <input type="text"/>
7. Carotid artery for surgery is asymptomatic*	<input type="checkbox"/>	<input type="checkbox"/>		

* Asymptomatic = the CAROTID artery for surgery has NEVER ever had any symptoms

* Asymptomatic = if the patient has ONLY had vertebrobasilar stroke or TIA. (This artery by definition is asymptomatic.)

(tick all that apply)

8. Infarct visible on CT or MRI? None visible
 Yes, on Right Side of brain
 Yes, on Left Side of brain
 or CT/MR not done

THE CAROTID ARTERIES (The ECST method for measuring % carotid stenosis is shown in your trial information pack. **Use ECST criteria, or equivalent**)

(tick all that apply)

9. Method of assessment of stenosis: Ultrasound
Catheter Angiography
MR Angiography
CT Angiography

10. Right carotid artery: % stenosis % **OR** if artery is completely blocked tick box →

11. Left carotid artery: % stenosis % **OR** if artery is completely blocked tick box →

12. Carotid artery scheduled for operation: Right *(please tick one box)*
Left

RISK FACTORS *(Please tick one box for each line)*

	YES	NO
13. Hypertension? (on treatment or systolic BP ≥ 160 mmHg or diastolic ≥ 90 mmHg)	<input type="checkbox"/>	<input type="checkbox"/>
14. Diabetes? (on treatment or any blood sugar ≥ 10 mmol/litre or ≥ 180 mg%)	<input type="checkbox"/>	<input type="checkbox"/>
15. Peripheral arterial disease?	YES	NO
15 (a) - claudication ever?	<input type="checkbox"/>	<input type="checkbox"/>
15 (b) - previous peripheral arterial surgery?	<input type="checkbox"/>	<input type="checkbox"/>
15 (c) - previous peripheral angioplasty?	<input type="checkbox"/>	<input type="checkbox"/>

	YES	NO
16. Aortic aneurysm ever?	<input type="checkbox"/>	<input type="checkbox"/>
17. Chronic lung disease?	<input type="checkbox"/>	<input type="checkbox"/>
18. History of angina?	<input type="checkbox"/>	<input type="checkbox"/>
19. Previous myocardial infarction?	<input type="checkbox"/>	<input type="checkbox"/>
20. Previous coronary surgery or angioplasty?	<input type="checkbox"/>	<input type="checkbox"/>
21. Awaiting coronary surgery or angioplasty?	<input type="checkbox"/>	<input type="checkbox"/>
22. Cardiac failure now or in the past?	<input type="checkbox"/>	<input type="checkbox"/>
23. Atrial fibrillation now or in the past?	<input type="checkbox"/>	<input type="checkbox"/>
24. Current smoker (within last 12 months)?	<input type="checkbox"/>	<input type="checkbox"/>
25. Lifetime non-smoker?	<input type="checkbox"/>	<input type="checkbox"/>

26. Blood pressure Systolic | _____ | mmHg
Diastolic | _____ | mmHg

27. **AMERICAN SOCIETY OF ANAESTHSTISTS CLASSIFICATION - Physical condition**
ASA GRADE

	<i>(please tick one box only)</i>
I Normally healthy patient with localised condition requiring surgery	<input type="checkbox"/>
II Patient with mild or well controlled systemic condition e.g. mild hypertension	<input type="checkbox"/>
III Patient with severe systemic condition limiting lifestyle e.g. angina	<input type="checkbox"/>
IV Patient with severe systemic condition threatening life e.g. advanced cardiac disease	<input type="checkbox"/>
V Moribund patient not expected to survive 24 hours with or without operation	<input checked="" type="checkbox"/> (DO NOT RANDOMISE)

Either Fax or Telephone your Randomisation:

Fax Randomisation: please fax both pages of this form to the GALA Trial Office, Fax number: + 44 (0) 131 332 5150. The allocation will be faxed back to you within one working day.

Telephone Randomisation (24hour service): telephone + 44 (0) 131 537 2922 to randomise your patient.

Once the allocation is received please check one of the boxes below and place this form in the patient's file. Thank you.

Remember: You must fax the Patient's signed and witnessed consent form to the Trial Office + 44 (0) 131 332 5150

FOR GALA TRIAL OFFICE USE ONLY

This patient has been randomised to:

GENERAL ANAESTHESIA **LOCAL ANAESTHESIA**