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An international multicentre randomised trial comparing general anaesthetic versus local anaesthetic for carotid surgery

Submission date 12/09/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2002	**Overall study status** Completed	
Last Edited 31/12/2008	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2268/1979

Study information

Scientific Title

Acronym
GALA

Study objectives
A prospective, randomised trial of local versus general anaesthesia for carotid endarterectomy is proposed to determine whether the type of anaesthesia does indeed influence peri-operative morbidity and mortality, quality of life and long term outcome in terms of stroke-free survival.

Please note that as of 29/05/2008 this record was updated to include a longer recruitment period. All changes can be found under the relevant fields, with the update date of 29/05/2008. The anticipated end date of this trial was extended to 30/04/2008. The previous anticipated end date of this trial was 31/12/2006. Randomisation stopped on 31/10/2007 and the presentation of results is expected on 06/09/08.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Northern and Yorkshire MREC on the 28th August 1998 (pilot phase) and 22nd April 2003 (main phase).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Carotid stenosis (at risk from stroke)

Interventions
Anaesthetic for surgery - local versus general. Randomisation will be by telephone to the trial office. Data will be collected at baseline (prior to randomisation) and this will include demographic details, known risk factors, diagnostic procedures and findings, and indications for surgery. The follow-up data will be collected when the patient is discharged from acute care, and operative details and any early complications will be recorded. At 1 month post-surgery, a stroke physician, blind to the type of anaesthesia, will review the patient. Also the patient will be asked to complete a health related quality of life questionnaire including the widely used EuroQol and Short Form 36, plus a carotid endarterectomy (CEA) specific questionnaire designed to capture patient satisfaction levels with the method of anaesthesia. Length of time spent in the recovery room, intensive care unit (ICU) and high dependency unit (HDU), and length of overall acute hospital stay will be recorded. Annual follow up will be by post to the family doctor and to the patient, seeking details of any strokes.

Intervention Type

Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
The proportion of patients alive, stroke free (including retinal infarction) and without myocardial infarction (MI) 30 days post-surgery.

Key secondary outcome(s)
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.

Completion date
30/04/2008

Eligibility

Key inclusion criteria
The main criterion for entry into this study is that, in the opinion of the responsible clinician, the patient requiring an endarterectomy is suitable for either local or general anaesthesia, and there is no clear indication for either type. All patients with either symptomatic or asymptomatic internal carotid stenosis for whom surgery is advised are eligible. There is no upper age limit.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Failure to obtain informed consent
2. Patient unable to co-operate with awake testing during local anaesthesia
3. Patient considered unfit for general anaesthesia
4. Patient considered unfit for local anaesthesia
5. Patient requiring simultaneous bilateral carotid endarterectomy
6. Carotid endarterectomy combined with another operative artery bypass surgery
7. Patient has been randomised into the trial previously

Date of first enrolment
01/06/1999

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Australia

Austria

Belarus

China

Croatia

Czech Republic

Estonia

Georgia

Germany

Greece

Hungary

Israel

Italy

Latvia

Netherlands

Poland

Portugal

Saudi Arabia

Slovakia

Spain

Sweden

Türkiye

Ukraine

Study participating centre
Neurosciences Trials Unit
Edinburgh
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Sponsor information

Organisation
The Health Foundation (UK)

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/12/2008		Yes	No
Protocol article	Protocol	21/05/2008		Yes	No
	Study website				

Study website	11/11/2025	11/11/2025	No	Yes