ISRCTN00525237 https://doi.org/10.1186/ISRCTN00525237

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

Study website
http://www.galatrial.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
01/06/1999

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

Age group
Adult

Sex
Both

Target number of participants
5,000 (as of 19/05/08, the total recruited: 3,526)

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
Australia

Austria

Belarus

China

Croatia

Czech Republic

Estonia

Georgia

Germany

Greece

Hungary

Israel

Italy

Latvia

Netherlands

Poland

Portugal

Saudi Arabia

Scotland

Slovakia

Spain

Sweden

Türkiye

Ukraine

United Kingdom

Study participating centre
Neurosciences Trials Unit
Edinburgh
United Kingdom
EH4 2XU

Sponsor information

Organisation
The Health Foundation (UK)

Sponsor details
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WC2E 9RA
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Sponsor type
Charity

Website
http://www.pppfoundation.org.uk/

ROR
https://ror.org/02bzj4420

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	Protocol	21/05/2008		Yes	No
Results article	results	20/12/2008		Yes	No