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# In patients undergoing carotid endarterectomy under general anaesthesia, does superficial cervical plexus blockade with the local anaesthetic bupivicaine affect post-operative blood pressure control?

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>17/04/2015 | **Condition category**<br>Surgery | [ ] Individual participant data<br>[ ] Record updated in last year |

**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**

N0227149022

# Study information

### Scientific Title
In patients undergoing carotid endarterectomy under general anaesthesia, does superficial cervical plexus blockade with the local anaesthetic bupivicaine affect post-operative blood pressure control?

### Study objectives
In the early post-operative period following carotid endarterectomy, patients commonly develop blood pressure liability. It is our observation that over the last 2 years the incidence of severe hypertension requiring treatment appears to have decreased whilst the incidence of hypotension appears to be increasing. There are two main changes to our practice that may be contributing to this observation: Firstly, the vast majority of our patients are now beta-blocked as this has been shown to improve outcome in patients undergoing vascular surgery. Secondly, our patients are now commonly given a superficial cervical plexus block in addition to a general anaesthetic as part of a multi-modal approach to post-operative analgesia. We would like to look at the influence of superficial cervical plexus blockade on post-operative blood pressure control in these patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Primary study design
Interventional

### Study design
Randomised controlled trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Surgery: Carotid endarterectomy

### Interventions
All patients undergoing carotid endarterectomy will receive a standardised general anaesthetic.

The patients in the study will be randomised to the treatment group who will receive a superficial cervical plexus block, or to a control group receiving no block.

This block will be performed in the anaesthetic room following induction of anaesthesia by the responsible anaesthetist using a standard block technique. Following surgery the patients will be monitored in recovery in the usual manner until stable before being transferred to the high dependency unit for the first 24 hours following surgery. Any pain will be treated with intravenous opiates or simple analgesics as appropriate. Blood pressure persistently greater

than 160mmHg will be treated with labetolol or GTN. Hypotension persistently below 100mgHg will be treated with a fluid challenge and phenylephrine, according to the current HDU guidelines.

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Bupivicaine

### Primary outcome(s)
Mean systolic blood pressure over the first 24 hours following surgery.

### Key secondary outcome(s)
Secondary outcomes will include the need for vasopressor or antihypertensive medication, cumulative opiate requirements, and mean pain scores in recovery and HDU.
Any major cardiovascular or cerebrovascular morbidity or mortality in the first 24 hours, and any side effects potentially related to the block will be recorded.

### Completion date
30/09/2007

## Eligibility

### Key inclusion criteria
The patients will be selected from all patients presenting for carotid endarterectomy. The vast majority of these patients are now seen in the vascular preadmission clinic by a consultant anaesthetist. This clinic will provide the opportunity to discuss the project with the patients. They would then be able to consider at home prior to admission whether or not to participate. Consent where relevant would then be taken at the time of admission. Approximately 100 patients undergo this operation annually in the trust. We need to recruit at least 54 patients and we would hope to achieve this over 1 year.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### Key exclusion criteria

Patients will be excluded if they have a contraindication to a block, such as coagulopathy, thrombocytopenia, treatment with clopidogrel or multiple anti-platelet agents within one week of surgery. Other exclusions will be patient refusal and known local anaesthetic allergy. In order to account for the potential influence of beta-blockade, only patients on perioperative beta blockade will be studied. Patients will therefore be excluded if they have a contraindication to beta-blockade.

1. Patients will be excluded if they do not wish to take part in this trial
2. Contra-indication to beta blockage therapy
3. Increase risk of bleeding (ie patients with low platelet counts , coagulopathy associated with liver dysfunction, treatment with multiple antiplatelet agents or treatment with clopidogrel in the 7 days prior to surgery)
4. Patients with known allergy to local anaesthetics

### Date of first enrolment
01/09/2004

### Date of final enrolment
30/09/2007

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**South Tees Hospital Trust**
Middlesbrough
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## Sponsor information

### Organisation
Department of Health

## Funder(s)

### Funder type
Government

**Funder Name**
South Tees Hospitals NHS Trust (UK)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration