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# The haemodynamic effect of superficial cervical plexus blockade in patients undergoing carotid endarterectomy under general anaesthesia

**Submission date**
02/11/2005

**Registration date**
28/11/2005

**Last Edited**
26/05/2011

**Recruitment status**
Stopped

**Overall study status**
Stopped

**Condition category**
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

## Study information

**Scientific Title**

## Study objectives
Carotid endarterectomy is performed in patients with severe stenosis (narrowing) of the carotid arteries. The operation improves blood supply to the brain and reduces the risk of stroke in selected patients. In the early post operative period following carotid endarterectomy patients commonly develop blood pressure lability. It is our observation that severe hypertension has decreased whilst hypotension requiring treatment has increased in our patient group over the past 2 years. Two changes in our practise may be contributing to this - first the majority of patients are now beta blocked, secondly our patients are now commonly given a superficial cervical plexus block. We aim to establish the influence of superficial cervical plexus blockade on post operative blood pressure control in these patients.

Our null hypothesis is that there is no clinically significant difference in the mean blood pressures in the first 24 hours following carotid endarterectomy in patients who have been given a superficial cervical plexus block and those who have not.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received on the 22nd July 2004; amendment approved 27th May 2005 (ref: 04 /Q1001/21).

## Study design
Randomised controlled double blind trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Blood pressure lability

## Interventions
Patients will receive a superfical cervical plexus block with either 2 mg/kg of laevo-bupivacaine or a placebo block with the equivalent volume of saline

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Laevo-bupivacaine

## Primary outcome(s)
Mean systolic blood pressures over the first 24 hours postoperatively.

## Key secondary outcome(s))

1. Need for antihypertensive treatment
2. Need for pressor treatment
3. Cumulative dose of any vasoactive medication
4. Mean pain scores
5. Cumulative opiate requirements

Any cardiovascular, cerebrovascular or other major morbidity or mortality occuring during the time period and any complication potentially related to the superficial cervical plexus block will also be recorded.

### Completion date
20/11/2006

### Reason abandoned (if study stopped)
Objectives no longer viable

## Eligibility

### Key inclusion criteria
Patients at James Cook University Hospital undergoing carotid endartectomy

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
Patients will be excluded if they:
1. Do not wish to take part
2. Are unfit for a general anaesthetic
3. Have a contraindication to either beta blockers or to being given a local anaesthetic block (e.g. local anaesthetic allergy and bleeding tendency)

### Date of first enrolment
20/11/2005

### Date of final enrolment
20/11/2006

## Locations

### Countries of recruitment
United Kingdom

England

**Study participating centre**
**Anaesthetic Department**
Middlesbrough
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# Sponsor information

**Organisation**
James Cook University Hospital (UK)

**ROR**
https://ror.org/02vqh3346

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
James Cook University Hospital (UK) - Anaesthetic Department

# Results and Publications

**Individual participant data (IPD) sharing plan**

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