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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	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/11/2005	**Overall study status** Stopped	
Last Edited 26/05/2011	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Mean systolic blood pressures over the first 24 hours postoperatively.

Secondary outcome measures
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.

Overall study start date
20/11/2005

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

Age group
Adult

Sex
Both

Target number of participants
54

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
England

United Kingdom

Study participating centre
Anaesthetic Department
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
James Cook University Hospital (UK)

Sponsor details
Cheriton House
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
Hospital/treatment centre

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

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