

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

Submission date 02/11/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/11/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/05/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gerard Danjoux

Contact details
Anaesthetic Department
Cheriton House
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
+44 (0)1642 850850 ext 4600
gerard.danjoux@stees.nhs.uk

Additional identifiers

Protocol serial number
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

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 occurring 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 endarterectomy

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

United Kingdom

TS4 3BW

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