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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

# 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

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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