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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?

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gerry Danjoux

Contact details
South Tees Hospital Trust
The James Cook University Hospital
Anaesthetics Department
Cheriton House
Marton Road
Middlesbrough
United Kingdom
TS4 3BW
-
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled 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

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 measure
Mean systolic blood pressure over the first 24 hours following surgery.

Secondary outcome measures
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.

Overall study start date
01/09/2004

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
54

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
England

United Kingdom

Study participating centre
South Tees Hospital Trust
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
South Tees Hospitals NHS Trust (UK)

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