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Preventive analgesia and recovery from anaesthesia

Submission date 06/11/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/11/2009	**Overall study status** Completed	
Last Edited 30/11/2009	**Condition category** Surgery	

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

Recovery after transition analgesia in patients undergoing carotid endarterectomy: comparison between anaesthetic superficial cervical plexus block and intravenous morphine

Study objectives
The anaesthesia in vascular patients undergoing carotid endarterectomy (CEA) should not only guarantee haemodynamic stability and absence of pain, but also allow early awakening and early neurological assessment.

One of the most used anaesthesia techniques to facilitate early recovery from anaesthesia is total intravenous anaesthesia (TIVA), which is performed using two short half time drugs namely remifentanil and propofol. Nevertheless, this kind of anaesthesia requires transition analgesia, usually with morphine, to guarantee a pain free recovery. Therefore, the advantage taken by the administration of short half life anaesthesia drugs may be lost due to the effect of transition analgesia.

The aim of this study is compare the number of patients with Aldrete Score greater than or equal to 8 in two groups of patients who will receive different technique of analgesia transition: the superficial cervical plexus block with levobupivacaine 7.5% 10 ml, or the intravenous administration of a standard dose of morphine.

Secondary objectives are to compare pain, nausea, vomiting, and shiver in the two groups at fixed points in time in the post-operative period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Azienda Ospedaliero-Universitaria di Ferrara, Ferrara, Italy, approved on the 27th July 2009

Study design
Single-centre randomised double blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Carotid endarterectomy

Interventions
A random number table will be generated by the computer. Accordingly, a physician not involved in data collection or patient-assessment, will prepare 64 sealed non-transparent envelopes, each reporting a code number and containing a sheet of paper reporting "Morphine" or "Block". The envelopes will be in a free deposit box in the office of the operative suite. The investigator administering morphine or performing the block will be the same and he will know the patient assignment after the induction of anaesthesia. At the end of surgery, the skin where the block was performed will be covered by plaster so the observer of the recovery period, not involved in the anaesthesia or aware of the patient group assignment, could not distinguish the technique used. The physician responsible for randomisation will maintain concealed the codes until the end of the study.

All patients enrolled will receive a standardised general anaesthesia. Anaesthesia monitoring will include electrocardiograms (ECG) (five derivations), invasive blood pressure measurement, saturation of peripheral oxygen (SpO2), train-of-four (TOF), Bispectral Index (BIS). Anaesthesia will be induced thought peripheral vein; after pre-oxygenation with fraction of inspired oxygen (FiO2) 1 through facial mask (3 minutes), remifentanil infusion (0.1 µg/kg/min) will be started and, after 5 minutes, a bolus of propofol (0.2 mg/kg intravenous [iv]) followed by cisatracurium (0.1 mg/kg iv) will be administered. The dosing of drugs will be calculated on the ideal weight (Broca formula): for man = height (cm) - 100; for woman = height (cm) - 104.

After tracheal intubation, patients will be mechanically ventilated with FiO2 0.5 in air, tidal volume 6 - 8 ml/kg, respiratory rate 12/min. General anaesthesia will be maintained with remifentanil and propofol infusion according to the required depth of anaesthesia.

Before starting surgery, the investigator will open the envelop containing the randomisation code, so patients will be assigned to one of the following two groups:
Group B: receive a superficial cervical block with levobupivacaine 7.5% 10 ml after induction of anaesthesia and before the surgical incision
Group M: morphine will be administered 30 minutes before the end of surgery, in a dose of 0.15 mg/kg iv in patients aged less than or equal to 75 age or 0.10 mg/kg in patients over 75 age.
The observer who will perform the post-operative assessment of the patient will not be involved in the anaesthesia or aware of the patient group assignment. About 60 minutes before the end of surgery, acetaminophen 1 g will be administered intravenously in 15 minutes to both groups. At the end of surgical operation, the decurarisation with prostigmine and atropine will be performed according to the TOF value and then the infusion of propofol and remifentanil will be interrupted (time T0).

In the recovery period, Aldrete score will be measured at 0, 5, 10, and 30 minutes after extubation. At the same time, respiratory rate (RR), heart rate (HR), pain (Numerical Rating Scale 0 - 10), nausea (yes or no), vomiting (yes or no), and shivers (yes or no) were recorded. Subsequently (60, 120, and 180 minutes after extubation), SpO2, RR, HR, arterial pressure, pain, nausea, vomiting and shivers will again be assessed. All of the assessments will be performed by an observer not involved in the anaesthesia or aware of the patient group assignment.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Aldrete score, measured at 0, 5, 10, and 30 minutes

Secondary outcome measures
Measured at 0, 5, 10, 30, 60, 120, and 180 minutes after extubation:
1. Respiratory rate (RR)
2. Heart rate (HR)
3. SpO2
4. Arterial pressure
5. Pain (Numerical Rating Scale 0 - 10)
6. Nausea (yes or no)
7. Vomiting (yes or no)
8. Shivers (yes or no)

Overall study start date
30/11/2009

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Patients aged 18 years or greater, either sex
2. Undergoing elective carotid endarterectomy
3. No contraindication to local anaesthetic block
4. Give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
32 patients per group (total: 64 patients)

Key exclusion criteria
1. Aged less than 18 years
2. Refusal
3. Urgent surgery (planned less than 24 hours in advance)
4. Patients with psychiatric pathology or inability to cooperate
5. Presence of contraindication to local anaesthetic block (i.e. allergy)

Date of first enrolment
30/11/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Italy

Study participating centre
Corso Giovecca 203
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Sponsor information

Organisation
University of Ferrara (Italy) - Department of Surgical, Anaesthetic and Radiological Sciences

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Sponsor type
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ROR
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Funder(s)

Funder type
University/education

Funder Name
University of Ferrara (Italy) - Department of Surgical, Anaesthetic and Radiological Sciences

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