

Preventive analgesia and recovery from anaesthesia

Submission date 06/11/2009	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 30/11/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/11/2009	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 Stefano Camerani

Contact details
Corso Giovecca 203
Ferrara
Italy
44121
s.camerani@ospfe.it

Additional identifiers

Protocol serial number
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 remifentanyl 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

Study type(s)

Treatment

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 through peripheral vein; after pre-oxygenation with fraction of inspired oxygen (FiO₂) 1 through facial mask (3 minutes), remifentanyl 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 remifentanyl and propofol infusion according to the required depth of anaesthesia.

Before starting surgery, the investigator will open the envelope 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 remifentanyl 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(s)

Aldrete score, measured at 0, 5, 10, and 30 minutes

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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
Ferrara
Italy
44121

Sponsor information

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

ROR
<https://ror.org/041zkgm14>

Funder(s)

Funder type
University/education

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration