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Effect of patient-controlled sedation with propofol on patient satisfaction

Submission date
27/03/2013

Recruitment status
No longer recruiting

Registration date
16/04/2013

Overall study status
Completed

Last Edited
16/04/2013

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A national survey carried out by the French Society of Anesthesia and Critical Care with INSERM showed that 15% of anesthetic acts in France were due to diagnostic procedures. Several authors have raised this issue because of the cost involved at national level. For invasive diagnostic radiology (angiography), the necessity of the presence of an anesthesiologist is highly controversial. The safety aspect is mentioned but it is questionable because accidents are rare (approximately 0.1%) in those procedures. This explains that, in many centres, an anesthesiologist can be reached in case of an incident but is not present during the whole procedure. Another justification is to improve patient comfort and satisfaction. Some patients do not want to be sedated because of the possibility of post interventional drowsiness and legal constraints related to the anesthetic action (visit 48 hours in advance, monitoring for several hours etc). This uncertainty about the desired level of sedation is reflected in a wide range of anesthesia practices, ranging from simple monitoring to deep sedation for arteriography. Controlled sedation the patient (also called PCS) is a method derived from patient-controlled analgesia or PCA. The advantage of this technique is to control the patient's level of sedation. This study assesses how well the PCS method works.

Who can participate?
Participants aged under 70 years, with ASA physical status below 3, a scheduled cerebral angiography, and a consultation with an anesthetist at least 48 hours before the procedure.

What does the study involve?
61 patients were randomly allocated to one of two groups: receiving propofol-based PCS (n = 33, 15 mg bolus in 9 s) or placebo-based PCS (n = 28, bolus of 1.5 mL of a 20% lipid emulsion in 9 s).

What are the possible benefits and risks of participating?
Possible benefits were an improve experience of the sedation and fast recovery. Potential risks were insufficient sedation or secondary effects of propofol.

Where is the study run from?
France, Public Hospital of Marseille, neuroradiology operating room.

When is the study starting and how long is it expected to run for?
The study started in January 2000 and was expected to last 6 months.

Who is funding the study?
There was institutional funding from AP-HM, Public Hospital of Marseille, Research Department.

Who is the main contact?
Dr Axel Maurice-Szamburski
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
00/15

Study information

Scientific Title
Effect of patient-controlled sedation with propofol on patient satisfaction: a randomised study

Study objectives
The aim of this study was to evaluate the difference in patient satisfaction, assessed by a specific and validated scale, using a propofol-based PCS compared to placebo-based PCS for diagnostic cerebral angiography.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethical approval n°:00/15, Chairperson Pr. J-C Manelli, Ethical Committee: CPP Sud-Méditerranée II - Hôpital Salvator, Marseille, France.

Study design
Prospective double blinded randomised

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Diagnostic cerebral angiography

Interventions
We randomly assigned 61 patients to receive propofol-based PCS (n = 33, 15 mg bolus in 9 s) or placebo-based PCS (n = 28, bolus of 1.5 mL of a 20% lipid emulsion in 9 s).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The main objective was to evaluate whether a propofol-based PCS would lead at least to 20% difference in patients satisfaction on the EVAN scale, which was self reported the day after the procedure.

Secondary outcome measures
Secondary objectives were to assess the quality of patient conditioning by the neuroradiologist and the anesthetist and to report possible side effect.

Overall study start date
01/01/2000

Completion date
01/07/2000

Eligibility

Key inclusion criteria
1. Age under 70 years
2. ASA physical status below 3
3. Scheduled cerebral angiography
4. Consultation with an anesthetist at least 48 hours before the procedure

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Age under 18 years,
2. Emergency context
3. History of psychiatric disease
4, Long-course anxiolytic treatment
5. Counter-indication to propofol
6. Withdrawal of consent

Date of first enrolment
01/01/2000

Date of final enrolment
01/07/2000

Locations

Countries of recruitment
France

Study participating centre
264 rue St. Pierre
Marseille
France
13009

Sponsor information

Organisation
Assistance Publique Hôpitaux de Marseille AP-HM (France)

Sponsor details
264 rue St.Pierre
Marseille
France
13005

Sponsor type
Hospital/treatment centre

Website
http://www.ap-hm.fr

ROR
https://ror.org/00pg5jh14

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Institutional funding from AP-HM, Public Hospital of Marseille, Research 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results results	01/06/2005		Yes	No

Results article	01/01/2013	Yes	No