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OBTAIN

Occurrence of Bleeding and Thrombosis during Antiplatelet therapy In Non-cardiac surgery

Investigators

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The Aim of the Study

The OBTAIN study will examine the risks and benefits of continuing antiplatelet treatment in patients presenting for non-cardiac surgery who have one or more coronary artery stents in situ. The risks of perioperative major adverse cardiac events (MACE) in patients who discontinue antiplatelet drugs will be compared with the risk of intraoperative and postoperative bleeding in patients who continue these drugs.

The Clinical Problem

Percutaneous coronary intervention (PCI) has revolutionised the management of coronary artery disease but has brought with it difficult challenges for the anaesthetist.

It is not clear from current evidence if patients who have undergone PCI and are now to undergo non-cardiac surgery should have antiplatelet drugs continued through the perioperative period. If antiplatelet agents are stopped the patient is at a markedly increased risk of perioperative cardiac events (MACE). If they are continued the risk of intraoperative and postoperative bleeding may be increased.

The Size of the Problem

- 1.6 million PCI procedures will be performed in Europe in 2010
- Up to 5% of patients presenting for some types of non-cardiac surgery may have a coronary stent in situ.

The OBTAIN Study

The OBTAIN study is designed to tell us the best antiplatelet therapy to give to patients who have undergone PCI and now require non-cardiac surgery.

- Anaesthetists in participating centres will identify patients presenting for non-cardiac surgery who have coronary stents in situ and record details of their cardiac disease, antiplatelet agents and cardiac and bleeding complications.
- The statistical technique of propensity scoring will be used to match patients according to their antiplatelet therapy.

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- The incidence of Major Adverse Cardiac Events (MACE) and bleeding will be compared between patients on different antiplatelet treatments.
- The safest antiplatelet strategy for non-cardiac surgery patients will be determined.

The Size of the Study

- We plan to study 1,400 patients
- At least 50 centres across all European countries will be needed

Inclusion Criteria

- Patients undergoing non-cardiac surgery within four years of PCI with the placement of a bare metal or drug eluting stent

Exclusion Criteria

- Patients maintained on anticoagulant therapy e.g. heparin infusion before and after surgery. (This does not include the use of a bolus dose of heparin during vascular surgery or low dose heparin for thromboprophylaxis.)
- Patients receiving bridging therapy with heparin or other drugs to compensate for the withdrawal of antiplatelet drugs.

Becoming a Local Investigator

- OBTAIN is one of four studies selected to launch the ESA Clinical Trials Network. All ESA members who have a relevant clinical practice are invited to participate.
- You can register to participate in the study in person at the ESA-CTN Booth at the Helsinki Congress or by e-mailing [INSERT ESA-CTN E-MAIL HERE].
- Data collection will use a tick-box form and electronic data transfer to avoid excessive paperwork.
- All centres and investigators that have contributed patients will be listed on the study website and the major publications from the study.
- All successfully recruiting centres will be identified as potential sites for future ESA Clinical Trials Network Studies

UNIVERSITY OF LEEDS

Erasmus MC
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Further information: www.euroanaesthesia.org and research@euroanaesthesia.org

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PERISCOPE

Prospective Evaluation of a RIsk Score for postoperative pulmonary COmPlications in Europe

A 7-day data collection, prospective, observational study

Steering Committee:
Jaume Canet (Spain), Jonathan Hardman (United Kingdom),
Sergi Sabaté (Spain), Olivier Langeron (France),
Marcelo Gama de Abreu (Germany), Lluis Gallart (Spain),
Javier Belda (Spain), Klaus Markstaller (Germany),
Paolo Pelosi (Italy), Valentin Mazo (Spain).

What is the medical problem?
Postoperative pulmonary complications (PPCs) account for a substantial proportion of risk related to surgery and anaesthesia and are a major cause of postoperative morbidity and mortality and longer hospital stays. The incidence rates ranges between 2% and 40%, depending on the type of patients and surgery. The factors affecting the development of PPC are related to the prior health status of the patient and the effects of anaesthesia and surgical trauma. The synergy between these factors determines risk.

What is the interest for studying prediction of PPC?
Until now, there exists no definitive study providing a simple score for predicting PPC useful in any clinical setting. Identifying patients at risk of PPC is an important step toward improving surgical safety, because we can establish a perioperative strategy to reduce the risk individually.

What is the hypothesis?
It is possible to generalize the preoperative use of a simple score, built up from a clinical set of variables, to predict PPC.

What is the objective?
In 2006, in Catalonia, a prospective study on postoperative outcome in a representative general surgical population (ARISCAT study) found a 5% incidence of PPC. The 30-day mortality of patients with PPC was 20%. The ARISCAT also identified 9 independent risk factors for PPC (age, male sex, low preoperative SpO_2, acute respiratory infection during the previous month, preoperative anaemia, positive cough test, upper abdominal or intrathoracic surgery, surgical duration ≥2 hours and emergency surgery). A simplified risk score was derived for each variable.
The main objective is to validate a risk index based on nine objective and easily assessed factors, described in the ARISCAT study, in a general unrestricted surgical population across Europe, to accurately predict PPC in any clinical setting.
Secondarily, this multinational prospective study will allow knowing the variability of the PPC rate among the different countries in Europe.

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Patients:
Patients undergoing a non-obstetric in-hospital surgical procedure, elective or emergent, under general or regional (neuraxial or plexus) anaesthesia.
Exclusions: a) age <18 years; b) obstetric procedures or any procedure during pregnancy; c) procedures in which only local or peripheral nerve anaesthesia was used; d) procedures outside the operating room; e) procedures related to a previous postoperative complication; f) transplantation; g) patients with preoperatively intubated trachea; and h) outpatient procedures.

What will the outcomes be?
The main outcome, defined as a PPC, will be a composite of the in-hospital fatal or non-fatal postoperative events. This composite will include: respiratory infection, respiratory failure, bronchospasm, atelectasis, pleural effusion, pneumothorax or aspiration pneumonitis. The investigators will identify them by consulting medical records and looking for events that fulfilled any PPC definition.
The secondary outcomes will be postoperative length of stay and in-hospital mortality rate.

Data collection
A centralized database and applications for remote data recording must be developed incorporating quality control algorithms to validate online data entry and identify missing data. A data manager will check entries and asked local teams to confirm completeness of records. A questionnaire of variables and definitions will be developed. The following information will be collected and the ARISCAT score calculated for each patient:
Administrative: Date of surgery and date and status (alive or dead) at hospital discharge.
Demographic: Gender and birth date.
Preoperative: Preoperative SpO_2 breathing air in supine position, respiratory infection in the last month, preoperative haemoglobin and cough test (the patient is told to take a deep breath and cough once. A positive test is defined by repeated coughing after the first cough).
Intraoperative: Surgical incision: intrathoracic , upper abdominal or peripheral, surgical duration and type of surgery (scheduled or emergency).
Postoperative outcome: Postoperative pulmonary complications, according to the definitions previously stated.
Other additional information: ASA class, height and weight, smoking status, chronic pulmonary disease, description of the surgical procedure, surgical specialty and anaesthetic technique.

Sample size
According to the ARISCAT study, the PPC incidence was 5%. We need at least 100 PPC for a decrease in c-statistics of 0.1. Then, the minimum sample size required will be around 2000 individuals. To find differences among countries or geographical areas we need 2000 individuals for each one.

Centres
All centres in Europe will be welcome to participate in the study. **Each applicant centre must recruit for a week** (7 days) all patients meeting inclusion and exclusion criteria. The week assigned will be previously randomized.
At least a responsible local investigator must be designated and a national coordinator will be the leader maintaining continuous contact with the centres and the steering committee.

Ethical Considerations
Due to the nature of the study, no ethical concerns exist. All patients will receive routine care; no research-related intervention will be introduced. Institutional approval will be required to each participating centre in order to get permission for collecting observational clinical information.

Further information: www.euroanaesthesia.org and research@euroanaesthesia.org

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PAIN-OUT

Incidence and risk factors of chronic post surgical pain: a European follow up study

The medical problem

Over the past ten years there has been recognition that chronic post-surgical pain (CPSP) is a significant medical problem. CPSP has an estimated mean incidence of 30% with variation depending on the type of surgery. The incidence of severe CPSP with functional impairment is estimated to be 5-10%. Every year, surgery is performed on over 30 million patients in the European Union, therefore the number of patients potentially exposed to CPSP is large and CPSP may represent a major, largely unrecognised clinical problem.

The PAIN OUT project (http://www.pain-out.eu/)

PAIN OUT is the first benchmarking project assessing management of postoperative pain at a European level. The existing network of PAIN OUT will collaborate with ESA CTN to improve understanding of the epidemiology and risk factors of CPSP. The group of PAIN OUT is composed of experts in the field of clinical research in acute pain. Their experience and already active collaboration in the PAIN OUT network offer a unique guarantee of success.

The objectives of PAIN OUT Long term follow up

Part one: assess the global incidence of chronic post surgical pain in a large sample of European patients, including rare types of surgeries and specific populations. Evaluate the differences in incidence patterns between European countries

Part two: determine the risk factors related to patient (clinical and genetic factors), surgery, anaesthesia and analgesia. Ascertain whether it is possible to define a predictive score for the incidence of CPSP and validate this score

Exclusion / inclusion criteria

All patients 18 years old and above, able and willing to participate in the study

Outcomes

Primary endpoint: incidence of CPSP 12 months after different types of surgeries

Secondary endpoints: risk factors of CPSP related to the patient, surgery, anaesthesia and analgesia

Sample size, study duration and participating centres

Patients recruited in the PAIN OUT project and the participating ESA CTN sites.

Each participating centre will have to include 50-100 patients a month.

Follow up at day one after surgery and a phone call at 12 months for Part 1.

Half of the PAIN OUT centres may participate.

We expect that 5 additional ESA CTN sites will participate.

This first phase will last two years for recruitment of patients and 3 months for analysis.

Phase two will be related to the results obtained in Part 1.

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How do you get involved?
Please contact Dominique Fletcher (chief investigator) by e-mail (dominique.fletcher@rpc.aphp.fr) or telephone ((1) 47107619; 0661177035) or through the ESA Secretariat (research@euroanaesthesia.org).

ESA and PAIN OUT need you!!

PAIN OUT

SEVENTH FRAMEWORK PROGRAMME

EUROPEAN COMMISSION
Community research

Further information: www.euroanaesthesia.org and research@euroanaesthesia.org

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European Surgical Outcomes Study (EuSOS)

An international seven day study of standards of care and clinical outcomes after non-cardiac surgery

Background

As many as 234 million major surgical procedures are performed worldwide each year. We know very little about the peri-operative care of these patients or their clinical outcomes. However, because so many procedures are performed, it is very likely that complications following major surgery are a leading cause of morbidity and mortality. Patients who develop complications but survive will still suffer reductions in functional independence and a substantial decrease in medium and long-term survival.

We urgently need to learn more about the differences in quality of peri-operative care across nations and to confirm the frequency of poor surgical outcomes. Without this robust epidemiological data many will not be convinced of the importance of good quality peri-operative care or the need for more research to improve this further. The mismatch in peri-operative care resource provision could be widespread or confined to just a few nations. Either way, because so many patients undergo surgery, even small improvements in their care could have a massive impact.

The EuSOS study will investigate peri-operative care across Europe to provide a very large but simple dataset. This data could trigger a step-change in the care of non-cardiac surgical patients and will provide a strong basis for new clinical trials to raise standards still further.

What questions will EuSOS answer?

EuSOS has been designed to answer a range of simple questions including:

- What is the in-hospital mortality rate for patients undergoing non-cardiac surgery?
- What is the duration of hospital stay for patients undergoing non-cardiac surgery?
- What is the current standard of peri-operative critical care provision non-cardiac surgery?
- What is the current standard of haemodynamic (cardiac output) monitoring?
- Are there differences in peri-operative care provision in different health-care systems?
- Are there differences in hospital stay and mortality following surgery in different nations?

How will the study work?

Hospitals will collect data describing the care of all adults undergoing in-patient non-cardiac surgery within a seven day period in the spring of 2011. We will include elective and non-elective surgery but exclude day-case surgery, cardio-thoracic surgery, neurosurgery, radiological or obstetric procedures. Each hospital will then be asked to provide information on the length of hospital and survival of these patients.

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Does it involve a lot of work?
In most hospitals, the study will work like a large clinical audit. We need to recruit a minimum of 150 hospitals in ten or more nations and it is important that the investigators in these hospitals are able to collect accurate data. We have taken care to request only information which is both useful and easy to collect. For most patients this will mean only a single one-page data sheet, easily completed by the anaesthetist in charge of each case. We will provide a user-friendly website to transfer the anonymous patient data to the lead centre.

What do you need from me today?
We are asking for volunteers to act as local co-ordinators in their hospitals, to ensure complete and accurate data collection which complies with local rules. Some volunteers will be invited to act as national co-ordinators in their own countries. All local and national co-ordinators must be approved by the EuSOS team.

How will I benefit from taking part?
Good question! The most important reason for taking part is to improve the standards of patient care; however there are some other benefits. Centres will receive an individual report allowing comparison of their dataset to that of their national cohort and the overall dataset. We hope to be able to offer free registration for a future ESA annual congress to the local co-ordinators in each hospital. Investigators will also be welcome to propose further analyses using the EuSOS dataset although these must first be approved by the EuSOS team. The work of all local and national co-ordinators will be publicly acknowledged.

How do I get involved?
Please provide your details on an expression of interest form or for more information, contact Rupert Pearse (chief investigator) by e-mail (r.pearse@qmul.ac.uk) or telephone (+44 20 7377 7299) or through the ESA Secretariat (research@euroanaesthesia.org).

Further information: www.euroanaesthesia.org and research@euroanaesthesia.org