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APRICOT

Anaesthesia PRactice In Children Observational Trial:
European prospective multicentre observational study:
Epidemiology of severe critical events

Steering Committee

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Medical problem

Despite the introduction of better-structured programmes for paediatric anaesthesia training and the development of some recommendations for paediatric anaesthesia services, the incidence of severe critical events in children is still unknown in Europe. Most studies published so far on morbidity and mortality in paediatric anaesthesia are the results of clinical audits focusing on a single institution or country. These single institution studies indicate often the incidence of critical events with minor morbidity but are not powered enough to inform about major complications and/or mortality.
Considering that the major life-threatening complications following general or regional anaesthesia are uncommon, it is therefore crucial to consider a large multicentre trial in order to establish a realistic statistical estimation and identify the risk factors for the severe critical events.
Moreover, a number of studies have shown differences in paediatric anaesthesia practice in Europe. Their possible impact on the epidemiology of severe critical events in children will be elucidated by the present study in order to improve the quality and safety of anaesthesia in children.

Objectives

The aims of the APRICOT study are:

- To establish the incidence of severe critical events in children undergoing anaesthesia in Europe.
- To describe the differences in paediatric anaesthesia practice throughout Europe.
- To study the potential impact of this variability on the occurrence of severe critical events (e.g.: laryngospasm, bronchospasm, pulmonary aspiration, anaphylaxis, cardiovascular instability, drug error, neurological damage, cardiac arrest and post-extubation stridor).
- To improve the quality and safety of anaesthesia in children throughout Europe.

Study design

Prospective, observational, multi–centre cohort study.

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Inclusion Criteria

- Age: from birth to 15 years included
- All children admitted for an inpatient or outpatient procedure under general anaesthesia with or without regional analgesia
- Children admitted for a diagnostic procedure under general anaesthesia (such as endoscopy, radiology…)
- Children admitted out-of-hours for emergency procedures

Exclusion Criteria

- Children admitted directly from the intensive care units to the operating rooms
- Anaesthesia procedures in the intensive care unit settings

Outcomes

Primary endpoint
- Incidence of severe critical events as an incidents occurring during and up to 60 minutes after anaesthesia or sedation (laryngospasm, bronchospasm, pulmonary aspiration, drug error, anaphylaxis, cardiovascular instability, neurological damage, cardiac arrest and post-extubation stridor) during and immediately following anaesthesia (PACU)

Secondary endpoints
- Risk factors for the occurrence of severe critical events (up to 60 minutes afterwards).
- Consequences of the critical events: no repercussion, minor aftermath, irreversible damage, in-hospital mortality up to 30 days or discharge.

Sample Size and Centres

This study will recruit as many participating institutions as possible across the 30 European countries represented at the ESA Council. It is plan to recruit at least 25,000 children over a period of two consecutive weeks including weekends and after-hours. The 2-weeks recruitment period will be chosen by each site to occur as of April 2014.

We anticipate that a total number about 200 centres will be needed to include between 20 and 200 children over the 2 weeks. Each centre will have a local and a national coordinator who will ensure that all participating centres in her/his country are in accordance with the study protocol.

Current Study Status:
324 centres in 37 nations are taking part in the study. 27 centres have started in April or May 2014 and 20 centres are currently planned to start soon! The study has been approved by the Belgian, Swiss and many other Ethics Committees and submission is ongoing in other countries. At the moment more than 1300 patients have been entered in eCRF. We will be glad to share our experiences with you during the Euroanaesthesia 2014 in Stockholm; you can meet us at ESA CTN stand on Sat. 31/5 from 11.30 to 13.30 and Sunday 1/6 from 10.30 to 12.30.

More information?
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