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

This study sponsored by the European Society of Anaesthesiology and endorsed by the European Society for Paediatric Anaesthesiology

research@esahq.org
Study Steering Committee

Back: K. Boda (HU), B. Leva (BE-ESA), K. Becke (DE), M. Zielinska (PL), E. Vermeulen (NL), S. Damster (BE-ESA)
Front: N. Morton (UK), F. Veyckemans (BE), W. Habre (CH)
Missing on the picture: T. Hansen (DK), M. Jöhr (CH), P. Marhofer (AU), E. Schindler (DE)
Study Aims

- Establish incidence of severe critical events in children undergoing anesthesia in Europe. (laryngospasm, bronchospasm, pulmonary aspiration, anaphylaxis, cardiovascular instability, drug error, neurological damage, cardiac arrest and post-extubation stridor).
- Describe differences in paediatric anaesthesia practice throughout Europe.
- Study the potential impact of this variability on the occurrence of severe critical events.
- Improve the quality and safety of anaesthesia in children throughout Europe.
Inclusion Weeks

Variable inclusion weeks

14-day inclusion period can be between 1 April and 31 DEC 2014

Each Institution chooses its own inclusion period independently

e.g. – Brussels Inst.X : From Tuesday 2 April at 7:00AM to Tuesday 21 April at 6:59AM
- Liège Inst.W : From Monday 1 Sep at 7:00AM to Monday 15 Sep at 6:59AM
- Paris Inst.Z : From Monday 17 Dec at 7:00AM to 31 Dec at 6:59AM
Study documents

LATEST DOCUMENTS:

➢ PROTOCOL version 1.2 = 24 JAN 2014

➢ CRF version 1.4 = 28 MAR 14

Sample Size

- Incidence of 0.1% of severe critical events
- Sample Size of 25,000 patients
- Allows to detect a 3 times increase in the probability of severe critical events due to difference in practice with a power of 0.9 and alpha error of 0.05

- Expected inclusions per centre: 20 to 200 patients
- At least 200 centres needed
### APRICOT sites

#### 322 sites in 37 nations

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<td><strong>Grand Total</strong></td>
<td><strong>322</strong></td>
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TIP: List of centres is available on this web-page
http://www.esahq.org/research/clinical-trial-network/ongoing-trials/apricot/status/
Participating Countries
Study logistics: centre

Each centre should go through the following mandatory steps:
1. Be listed on the list of participating Centres (call for new centre is closed)
2. Have 1 ESA Membership (active or associate) more info: here
3. Site questionnaire: www.surveymonkey.com/s/APRICOTSTUDY
5. Approval docs: Each centre must send 2 things 1. letter of ethics approval/notification 2. the APRICOT coversheet (see next slide) more info here
6. Send eCRF user list: Max 3 eCRF profiles per hospital. Inv. + 2 additional collaborators (provide family name, given name and email addresses)
7. Indicate to ESA the 2 weeks recruitment for your centre: choose your inclusion period within a time window of 9 months: 2 weeks between 01 April to 31 Dec 2014. (Inform ESA at least 1 week before planned start)

No eCRF access will be sent to centres if any of the above items is missing.
Study Logistics: EC/IRB Approval

When EC/IRB Approval is obtained, please send to ESA:

1) Documentation Coversheet available on this page

2) Proof of ethics approval (in local language is OK)

If 1 National Approval is sufficient:

Mention all approved institutions and physicians

No budget to support local submission costs

Centre #: A xxx-xxx
3 digit code for the country, 3 digit code for the hospital
Study Organization

National Coordinator

– Recruiting centres
– Translation study documents
– Ensure local E.C. and IRB approvals are obtained
– Assist and monitor local centres: coaching!
– Coordinate data cleaning process

TIP: List of NC responsibilities is available on
## Who is my National Coordinator?

<table>
<thead>
<tr>
<th>Country</th>
<th>LAST NAME of National COORDINATOR (NC)</th>
<th>First name NC</th>
<th>e-mail NC</th>
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Who is my National Coordinator?
Study Organization

Site Coordinator role

– Provide local leadership
– Ensure local E.C. and IRB approvals are obtained
– Assist and monitor local research group
– Guarantee integrity of data collection
– Ensure timely completion dataset
– Coordinate local data cleaning process
– Safe collection of data on site for 10 years

TIP: List of local Coordinator responsibilities is available on http://www.esahq.org/research/clinical-trial-network/ongoing-trials/apricot/faq-guidance/
Monitoring

Local Monitoring
– No on-site monitoring by study management
– Responsibility of site coordinator locally
– Responsibility of N.C. for all national centres

Data Monitoring
– Data checking and Cleaning
– By Chief investigator & ESA Data Management Team

Site Visit
– On-site visit by study Steering Committee members at random
Data Pool

Access to Complete Data Pool
– Provided after primary publication
– Judgment by Steering of planned secondary analysis
– Approval by Steering of final manuscript

Access to National Data Pool
– Available in consultation with National Coordinator

Access to Local Data Pool
– Available directly via Data Management Team
**Complete Data Pool :** Access to complete data-pool is provided after primary publication. After judgment by Steering of planned secondary analysis and approval by Steering of final manuscript.
Data Pool - National

National Data Pool: Access to national data pool is available in consultation with National Coordinator
**Local Data Pool:** Access to local data pool is available directly via data management team.
Authorship

– Collaborating authorship (see next 2 slides: PubMed)
– Each centre: at least 1 collaborating authorship
  but for every new set of 25 patients included
  → 1 extra collaborating authorship possible
Authorship

Mortality after surgery in Europe: a 7 day cohort study.


Abstract

BACKGROUND: Clinical outcomes after major surgery are poorly described at the national level. Evidence of heterogeneity between hospitals and health-care systems suggests potential to improve care for patients but this potential remains unconfirmed. The European Surgical Outcomes Study was an international study designed to assess outcomes after non-cardiac surgery in Europe.

METHODS: We did this 7 day cohort study between April 4 and April 11, 2011. We collected data describing consecutive patients aged 16 years and older undergoing inpatient non-cardiac surgery in 498 hospitals across 28 European nations. Patients were followed up for a maximum of 60 days. The primary endpoint was in-hospital mortality. Secondary outcome measures were duration of hospital stay and admission to critical care. We used χ2 and Fisher's exact tests to compare categorical variables and the t test or the Mann-Whitney U test to compare continuous variables. Significance was set at p<0.05. We constructed multilevel logistic regression models to adjust for the differences in mortality rates between countries.

FINDINGS: We included 46,539 patients, of whom 1865 (4%) died before hospital discharge. 3599 (8%) patients were admitted to critical care after surgery with a median length of stay of 1.2 days (IQR 0.9-3.6). 1358 (73%) patients who died were not admitted to critical care at any stage after surgery. Crude mortality rates varied widely between countries (from 1.2% [95% CI 0.0-3.0] for Iceland to 21.5% [16.9-26.2] for Latvia). After adjustment for confounding variables, important differences remained between countries when compared with the UK, the country with the largest dataset. (OR range from 0.44 [95% CI 0.19-1.05; p=0.06] for Finland to 6.92 [2.37-20.27; p=0.0004] for Poland).

INTERPRETATION: The mortality rate for patients undergoing inpatient non-cardiac surgery was higher than anticipated. Variations in mortality between countries suggest the need for national and international strategies to improve care for this group of patients.
Mortality after surgery in Europe: a 7 day cohort study.


Collaborators (1947)

Anonymized data

Coversheet
- Confidential Identification Log
- Attached to paper CRF
- Removed after data is logged in eCRF
- Stored separately from paper CRF
- Remains on site (10 years) (or more if locally required)
Case report Form = CRF

- Data collected 1\textsuperscript{st} on paper CRF
- Data transcribed from paper CRF to electronic CRF
  - Who? local staff
  - When? 2 months max after data collection end
- Paper CRF Stored in a locked place (separate from Coversheet)
Enrollment Criteria

• ALL consecutive patients from birth to 15 years old
• Inpatient or outpatient procedures
• Under sedation or general anaesthesia with or without regional analgesia or under regional anaesthesia alone.
• All diagnostic and surgical procedures
• In the OR or outside the OR
• Including an urgent or emergency procedure performed in- or out-of-hours

Exclusion Criteria

• Children coming intubated from the intensive care units
• Anaesthesia procedures in the intensive care unit settings
4.4 Protocol Flowchart: schematic diagram of trial design, procedures and stages:

- Exclusion criteria:
  - Children ≥ 16 years
  - Admission from ICU to OR
  - Procedures in ICU

- Data acquisition CRF 1
  - Pre-anaesthetic Consultation
    Patient’s Medical History
    (Informed Consent if applicable)

- Data acquisition CRF 2
  - Premedication
    Induction & Maintenance of Anaesthesia

- Data acquisition CRF 3
  - Severe Critical Events
    During Anaesthesia
    And in PACU up to 60 minutes

- Brain damage or permanent lesion
  In-hospital mortality or at discharge within 30 days

- Completion of eCRF

Day 0 data acquisition
CRF1:
- Pre-anaesthetic variables
  (demographic, medical history, indication, team in charge)
4.4 Protocol Flowchart: schematic diagram of trial design, procedures and stages:

- Elective, Emergency or Urgent Procedure
  - All children from Birth to 15 years

- Exclusion criteria:
  - Children ≥ 16 years
  - Admission from ICU to OR
  - Procedures in ICU

- Pre-anaesthetic Consultation
  - PATIENT’S MEDICAL HISTORY
    - (INFORMED CONSENT IF APPLICABLE)

- Data acquisition CRF 1

- Anaesthesia team in charge

- Premedication
  - INDUCTION & MAINTENANCE OF ANAESTHESIA

- Data acquisition CRF 2

- Day 0: surgery + 60 minutes after skin closure

- Severe Critical Events
  - DURING ANAESTHESIA AND IN PACU UP TO 60 MINUTES

- Data acquisition CRF 3

- From Day 0 to Discharge Day or Day 30 if patient still in hospital

- Brain damage or permanent lesion
  - IN-HOSPITAL MORTALITY OR AT DISCHARGE WITHIN 30 DAYS

- Completion of eCRF

- ! Definition of sedation vs Anaesthesia

Day 0: CRF 2
- Parameters related to the anaesthesia management, induction, maintenance, regional, airway, ventilation, fluids
4.4 Protocol Flowchart: schematic diagram of trial design, procedures and stages:

- **Elective, Emergency or Urgent Procedure**
  - Pre-anaesthetic Consultation
  - Day -1 or Day 0
  - Anaesthesia team in charge
  - Premedication
  - Induction & Maintenance of Anaesthesia

**Exclusion criteria:**
- Children ≥ 16 years
- Admission from ICU to OR
- Procedures in ICU

**Data acquisition CRF 1**

**Data acquisition CRF 2**

**Data acquisition CRF 3**

**TIP:** Print out the Appendix 5 ‘Definitions of Severe Critical events’ to place in the OR (you may want to translate)

**CRF4 Postoperative complications**
- Status at 30 days

**CRF3 Severe critical events**
- Bronchospasm, laryngospasm, pulmonary aspiration, drug error, anaphylaxis, cardiovascular instability, neurological damage, cardiac arrest, stridor
Frequently Asked Questions

You need more info or have a doubt on PROTOCOL? Please check the FAQ document on the ESA website. http://www.esahq.org/APRICOT

e.g. => Experience question

Experience: How many years the senior in charge has been practicing => I'm not sure how to answer this?

- for trainees: years since start of training
- for specialists (consultants) years since they achieved the Certification of Specialist Training in Anaesthesia (just before consultant job would start usually).
FAQ: 2 operations?

How to enter a patient if operated twice?

1. If multiple operations during the same anaesthesia procedure, please enter the patient only one time

2. If the patient is anaesthetised twice or more during the study period, patient is created once in the system but several occurrence of the CRFs are created for each additional anaesthesia. (e.g. major burn)
The electronic CRF data collection and management for ESA CTN Studies is performed using the OpenClinica open source software.

1. **Which browsers are Compatible?**
   - Internet Explorer 7: No  Google Chrome: No
   - Internet Explorer 8: Yes  Safari: No
   - Internet Explorer 9: No  Opera: No
   - Firefox >= v3.0: Yes

2. **Website security certificate error:**
   Sometimes you could have this message ‘There is a problem with this website’s security certificate.’ => choose ‘Continue to this website (not recommended)’
eCRF Password

Password are sent/reset from ESA Secretariat

Password confidentiality: 1 user = 1 password!

Up to 3 users per hospital (1 Investigator profile + 2 Data entry).

**TIP:** If there a true rationale why a site would exceptionally require more eCRF access: e.g. are there 2 separate buildings for enrolment or 2 separate units in a hospital that would justify the need for more access => Please contact ESA
To create or add a subject:

Navigate to « Subject Matrix » Click on « Add New subject », « the Pop up window: ‘Add New subject’ opens
Study Logistics:

**Login and Password**

**eCRF Add Subject from Task Menu**

- **Study Subject ID**: fill in identification number of the patient e.g. “032-005-123” => 032-005 is your centre number and 123 means it is first subject of your site

- **Secondary ID**: this is optional for local use if needed

- **Date of Enrollment/Start date**: Fill in date of anaesthesia procedure

- **Sex**: choose sex patient Male or Female. (optional)

Click on “Save and Assign Study Event”
Enter or Validate data

Click on the pen icon to enter or edit data

Click on the magnifier to view data
Date must always be in format DD-Mmm-YYYY (in English)

Or you can click on the calendar next to the date a calendar opens

ICF Applicable?
YES = mandatory by your ethics Committee
NO=Waiver/exemption received (ICF not needed)

TIP: it might seem to you that system is requesting again the same information as in the “Add New subject window” => Subject ID. Please note that subject ID, Sex, and dates here collected within eCRF pages are considered not the ones in the ‘Add New subject pop-up” window.

When you finish entering the data on the page, you must click on SAVE
e.g. If you select question 1 Type of procedure « Surgical » → Then only, you will be asked to indicate type of surgical procedure (1.1)

TIP: Some questions only appear on the eCRF from your responses to previous questions.
Mandatory items are indicated by red stars
If a data point is missing or outside the range (e.g. 35 cm – when minimum is set to 40 cm), upon pressing «Save» you will see a red exclamation mark and an error message on top of the page.

**TIP:** If you have several error messages in red on top of your screen, clicking on one error message will bring you to the field in error in the dataset.
After error message, you may want to correct the entered data then save or if you want you to confirm that your data is correct even if it is out of the present ranges, click on the blue flag a “discrepancy Note” will open. Enter the explanation of your aberrant value in the discrepancy note.
Discrepancy Notes/annotations can be used to justify missing data: If you want to leave a note for the Data Management Team press the flag (e.g. when mandatory data is missing).

You can save the page without receiving an error message.
When you finish all pages, you must select ‘Mark CRF complete’ at the bottom of the last page and hit “Save”. This will change the status of the eCRF from “data entry started” to “Complete”.

Mark eCRF “Complete”
Patient is anaesthetised twice or more?

1. Navigate to Subject Matrix
2. Enter the study subject ID
3. Click on the APRICOT CRF icon
4. Choose “Add Another Occurrence”

5. A “x2” appears on Subject Matrix beside the study subject
How to sign a subject?

1. Navigate to subject Matrix and in the Actions column
2. Click the “sign” icon
3. Enter User Name and Password
4. Click Submit

TIP: Sign Action depends on role of user, only Investigators can view the sign icon!
eCRF Test Instance Available

• The test-site is completely similar to the real instance.
• Please follow this link: https://www.esactn.org/OpenClinica_test/MainMenu
• There are 2 different test-users:
  • Local Investigator:
    User Name: INVESTTEST
    Password: INVESTTEST
  • Other Centre Staff (data entry):
    User Name: DATAENTRYTEST
    Password: DATAENTRYTEST

FULL eCRF guidance is posted on APRICOT website
ESA is the support for all eCRF questions
Website

ESA-CTN Website => APRICOT section

http://www.esahq.org/APRICOT
Thank you for your participation

ESA and APRICOT Study team
Do you have any questions?

Contact?

Medical questions related to study protocol; contact Prof. Walid Habre at Walid.Habre@hcuge.ch

Questions on documentation, translation, ethics approval, eCRF access; please contact Brigitte Leva, Sandrine Damster (+ Benoit Plichon) from the ESA Research Department at research@esahq.org

Questions on eCRF access or problems, contact the ESA OpenClinica Support Team at openclinicasupport@esahq.org