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ESA Clinical Trial Network

NECTARINE

NEonate-**C**hildren s**T**udy of **A**naesthesia p**R**actice **IN** **E**urope

Epidemiology of morbidity and mortality in neonatal anaesthesia:

A European prospective multicentre observational Study of clinical practice

Steering Committee

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Medical problem

Results of the recent prospective multi-centre observational study "APRICOT: Anaesthesia PRactice In Children Observational Trial (ClinicalTrials.gov identifier # NCT01878760)" will provide an insight into the incidence of severe perioperative critical events in children. More than 260 centres across Europe successfully contributed data for "APRICOT". The new Clinical Trial Network "NECTARINE" represents a natural extension of the APRICOT study and will specifically focus on the **neonatal** population.

Objectives

The primary aim of **NECTARINE** is to provide information on critical events, morbidity and mortality related to **neonatal anaesthesia**. Currently, the lack of validated 'normal' ranges for physiological parameters in neonates of different post-menstrual ages limits our ability to develop standardised policies and procedures for interventions based on predetermined values. NECTARINE will provide valuable information on the *need for specific perioperative interventions* triggered by the occurrence of *out-of-range physiological parameters*, the postoperative outcome at 30 and 90 days, and the predictors of critical events and poor outcome. Finally, NECTARINE will identify variations in clinical practice across Europe. Centres providing anaesthesia care for neonates and infants, including those that participated in the APRICOT study, will be invited to take part in this new study of the ESA Clinical Trial Network.

Design

Prospective, observational, multi–centre study of clinical practice.

Inclusion Criteria

The study population will include **all neonates and infants from birth to 60 weeks of post-menstrual age** (or 62 weeks for infants born after in-vitro fertilization) admitted to participating centres during a pre-determined 12-week recruitment period:

- all elective in-patient or out-patient surgical procedures performed under general anaesthesia with or without regional analgesia, or under sole regional anaesthesia;
- all cardiac and non-cardiac procedures;
- all diagnostic procedures performed under general anaesthesia;
- all urgent or emergency procedures performed in- or out-of-hours;
- all procedures performed in NICU/PICU under the care of an anaesthesiologist or directly admitted from the Intensive Care to the Operating Room.

Exclusion Criteria

- Infants aged over 60 weeks of postmenstrual age (or 62 weeks for infants born after in-vitro fertilization) on the day of anaesthesia.

Outcomes

Primary outcome

Perioperative interventions performed by the anaesthesia team aimed at treating a critical condition (the corresponding parameter or new clinical onset that triggered this intervention will be reported).

Secondary outcomes

1. 30-day and 90-day in and out-of-hospital morbidity and mortality in neonates undergoing anaesthesia.
2. Variability of clinical practice across Europe.
3. Occurrence of brain de-oxygenation by NIRS monitoring (when available);

Sample Size and Centres

This project will recruit as many participating institutions as possible across the 30 European countries represented by the ESA Council. It is planned to recruit about 5,000 patients over a 12-week observation period, including weekends and after-hours.
It is anticipated that at least 200 centres will be needed to achieve the target of patients during a 12-week period taking place from 01 March to 31 May 2016. Extra period of recruitments will be planned at a later stage. Local and national coordinators will ensure that all participating centres in their country have access to, and are familiar with, the protocol.

Sponsor

NECTARINE is entirely sponsored by a grant from the European Society of Anaesthesiology Clinical Trial Network (ESA CTN). The aim of the European Society of Anaesthesiology Clinical Trial Network is to provide an infrastructure for clinical research in the fields of Anaesthesia, Pain, Intensive Care and Emergency Medicine by transnational European collaborative studies.
The NECTARINE study has been endorsed by the following societies/organisations:
- European Society for Paediatric Anaesthesia (ESPA),
- Società di Anestesia e Rianimazione Neonatale e Pediatrica Italiana - S.A.R.N.eP.I.

More information?

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NECTARINE

ESPA
European Society for Paediatric Anaesthesiology

S.A.R.N.eP.I.
Società di Anestesia e Rianimazione Neonatale e Pediatrica Italiana

Further information:
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To register your Institution fill in the "Call for Centres form" online
www.esahq.org/ctnform

Register your Institution now!

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