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The CAPNO trial: a randomized controlled trial of two different methods of carbon dioxide detection in preterm infants in the delivery room

Submission date
09/02/2015

Recruitment status
No longer recruiting

Registration date
10/03/2015

Overall study status
Completed

Last Edited
15/01/2020

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
The adaptation that all infants are required to make upon entering life outside of the womb is complex. Many physiological changes have to take place for the newborn to survive outside their mother's womb once she has taken her first few breaths. Approximately 10% of all infants will require some help to make this adaptation. When an infant requires resuscitation, the heart rate is a factor that helps in determining what treatments (or interventions) may be needed. Although the use of non-invasive electrocardiography (ECG) monitoring is a standard of care in the neonatal intensive care unit (NICU), it's use is less well studied in the delivery room. Therefore, we hope to perform ECG monitoring in the delivery room on all infants included in this study. In some cases, the lungs of an infant may need assistance in making the transition to life outside of the womb and interventions such as positive pressure ventilation (PPV) may need to be made. PPV involves a member of the medical team placing a facemask around the infant's face and nose and providing gentle pressure to inflate the lungs, simulating the way an infant would inhale and exhale by themselves. Correct positioning of the infant's airway as well as an airway clear of obstructions are extremely important in making sure that the PPV an infant receives will be effective. At times, this intervention may be difficult to monitor, especially when the infant is small, such as when delivered at less than 32 weeks gestation. An indication of correct positioning of the airway, as well as an unobstructed airway, may be aided through the monitoring of end tidal carbon dioxide (EtCO2) that is produced by the infant when they exhale. This EtCO2 production can be monitored both qualitatively, as well as quantitatively, by means of two different non-invasive devices that are connected to the top of the face mask that is placed on the infant. This trial hopes to investigate both these devices and, in order to complete this investigation as effectively as possible, the device that each infant receives during their time in the delivery room will be randomised.

Who can participate?
Newborn infants of less than 32 weeks gestation.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive qualitative, in the form of a disposable end tidal carbon dioxide, (EtCO2) monitoring during resuscitation. Those in group 2 receive quantitative, in the form of side stream capnography, EtCO2 monitoring during resuscitation. All necessary EtCO2 equipment, is made available to the resuscitation team prior to delivery. All infants in both groups have their heart rate monitored by ECG.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Cork University Maternity Hospital (Ireland).

When is the study starting and how long is it expected to run for?
August 2014 to June 2015.

Who is funding the study?
investigator initiated and funded (Ireland).

Who is the main contact?
Professor Eugene Dempsey.

Contact information

Type(s)
Public

Contact name
Dr Eugene Dempsey

Contact details
Wilton
Cork
Cork
Ireland
n/a

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ECM 4 (ss) 03/06/14

Study information

Scientific Title
The CAPNO trial: a randomized controlled trial of exhaled carbon dioxide monitoring in the preterm infant.

Acronym
CAPNO (CAPNOgraphy in the Delivery Suite)

Study objectives
Carbon dioxide monitoring during the resuscitation of preterm infants improves the positive pressure ventilation (PPV) and results in improved short term outcomes, as determined by instances of normocapnia on admission to the neonatal intensive care unit (NICU)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethics Committee of the Cork Teaching Hospitals, Cork, Ireland, 18/05/2014, ref: ECM 4 (ss) 03/06/14

Study design
This single centre observational study will involve infants less than 32 weeks gestation and will take place in the delivery room of Cork University Maternity Hospital (CUMH). Participants will be randomised to receive qualitative, in the form of a disposable end tidal carbon dioxide (EtCO2) detector, or quantitative, in the form of side stream capnography, EtCO2 monitoring during resuscitation.

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact detailsto request a patient information sheet

Health condition(s) or problem(s) studied
Preterm birth

Interventions
EtCO2 monitoring during resuscitation is the intervention being investigated in this trial. Consent will be obtained at the antenatal stage from mothers who are expecting to deliver at less than 32 weeks gestation. Participants will then be randomised, by a trial investigator, prior

to delivery. All neccesary EtCO2 equipment, as decided by randomisation, will be made available to the resuscitation team prior to delivery. All infants, irrespective of randomisation, will have heart rate monitoring performed via electrocardiography.

Intervention Type
Device

Primary outcome measure
A reduction in the combined percentage of hypocapnia and hypercapnia within the first two hours of life, as measured by on blood gas analysis completed in the NICU

Secondary outcome measures
1. Heart rate via ECG and oxygen saturation (SpO2) at several 1 minute intervals, in the first few minutes of life
2. EtCO2 values for several 1 minute intervals in infants who were randomised to receive capnography, in the first few minutes of life
3. Completion and occurrences of resuscitation procedures via retrospective analysis of video recordings consented, by parents of the infant, to be obtained during the resuscitation
4. Analysis of the occurrence of intra ventricular haemorrhages (IVH), necrotising enterocolitis (NEC), bronchopulmonary dysplasia (BPD), and retinopathy of prematurity (ROP)

Overall study start date
01/08/2014

Completion date
30/06/2015

Eligibility

Key inclusion criteria
All mothers expected to have a preterm delivery of less than 32 weeks gestation will be approached for antenatal consent.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Mothers presenting with oligohydramnios (amniotic fluid index <5), suspected hypoplasia of the lungs and any known congenital anomalies of the fetus.
2. Failure to obtain consent.

Date of first enrolment
01/08/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Cork University Maternity Hospital
Cork
Ireland
-

Sponsor information

Organisation
Cork University Maternity Hospital Neonatology Dept

Sponsor details
Cork University Maternity Hospital
Wilton
Cork
Ireland
-

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04q107642

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded (Ireland)

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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No