

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/01/2020	Condition category Neonatal Diseases	<input type="checkbox"/> 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), its 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

Protocol serial number

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

Study type(s)

Diagnostic

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 necessary 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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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Sponsor information

Organisation

Cork University Maternity Hospital Neonatology Dept

ROR

<https://ror.org/04q107642>

Funder(s)

Funder type

Other

Funder Name

investigator initiated and funded (Ireland)

Results and Publications

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