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Breath carbon monoxide measurement in jaundiced newborns

Submission date
02/07/2018

Recruitment status
No longer recruiting

Registration date
20/07/2018

Overall study status
Completed

Last Edited
15/02/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
We are carrying out a study to measure breath carbon monoxide concentration in newborn infants who either have neonatal jaundice (hyperbilirubinemia) or are at risk for significant jaundice, a condition caused by excessive accumulation of a yellow pigment called bilirubin. High breath carbon monoxide concentration indicates increased breakdown of red blood cells (hemolysis), which is associated with increased risk of significant jaundice and subsequent brain damage. Phototherapy is required to eliminate significant jaundice, as infants with severe jaundice are at risk of permanent brain damage with life-long hearing impairment and cerebral palsy. Early identification of this helps with the timely initiation of phototherapy and to minimise the risk of brain damage. Our goal is to determine whether high breath carbon monoxide concentration is predictive of significant jaundice.

Who can participate?
We have planned to recruit 50 newborn infants born at 35 weeks of gestation or more with a birth weight of 2000 g or more, who are either jaundiced or at risk of significant jaundice.

What does the study involve?
After written consent from parents, infants will have two measurements of breath carbon monoxide concentration measurements 12-24 hours apart. All infants will have blood tests for serum bilirubin every 12-24 hours as decided by the treating physician. All infants with jaundice needing phototherapy will have full blood counts to assess for anemia and hemolysis as in usual treatment. Similarly, infants with blood group incompatibility (mother has blood group O and baby has blood group A or B) will have additional tests for antibodies.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part; however, there should be benefits to infants in future through improving neonatal jaundice management. Infants with high breath carbon monoxide levels will be monitored more closely for development of jaundice and early initiation of phototherapy. Infants with lower breath carbon monoxide levels can be discharged early from the hospital, therefore reducing the number of investigations. There are no known risks to participants taking part in this study.

Where is the study run from?
The study will be conducted at KK Women's and Children's Hospital in Singapore.

When is study starting and how long is it expected to run for?
March 2017 to December 2018. Participants will be enrolled on the study for a period of 6 months.

Who is funding the study?
The CoSense device (Capnia,Inc, Palo Alto, CA) used to measure breath carbon monoxide CoSense (Capnia,Inc, Palo Alto, CA) is being loaned to us by United Italian Trading Corporation (PTE) LTD, Singapore for the purpose of this study. Additionally, they have provided disposable nasal tubes for taking breath samples. The rest of the cost will be funded by research funds from the Department of Neonatology, KK Women's and Children's Hospital.

Who is the main contact?
Dr Ashwani Bhatia
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017/2734

Study information

Scientific Title
Early identification of hemolysis with ETCOc measurement in neonates at risk for severe hyperbilirubinemia

Study objectives

Physiological jaundice (hyperbilirubinemia) is common among newborns in the first week of life and requires monitoring. Early onset, rapidly rising or severe hyperbilirubinemia in neonates is a risk factor for neurotoxicity, especially if due to hemolysis. Bedside measurement of high breath end-tidal monoxide concentration (ETCOc) using a CoSense monitor in jaundiced neonates can provide evidence of increased hemolysis and will prove helpful in closer monitoring and early initiation of intensive phototherapy, and possibly avert exchange transfusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Centralised Institutional Review Board (CIRB), Singapore, 03/05/2018, CIRB Ref: 2017/2734

Study design
Observational cohort study

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 details to request a participant information sheet.

Health condition(s) or problem(s) studied
Neonatal hyperbilirubinemia (jaundice)

Interventions
After written consent from parents, infants will have two measurements of breath carbon monoxide concentration, the first within 12-24 hours of enrolment and the second 12-24 hours following this. These measurements will be taken using a portable CoSense device. All infants with jaundice requiring phototherapy will be tested for full blood counts and reticulocyte count to assess for anemia and hemolysis as per routine management. Similarly, infants with blood group incompatibility (mother has blood group O and baby has blood group A or B) will have additional tests for antibodies.

Intervention Type
Device

Primary outcome measure
1. ETCOc (Corrected end-tidal carbon monoxide) values, measured with a CoSense capnometer device. Two measurements will be taken, the first 12-24 hours after recruitment and the second 12-24 following the first measurement.

The following blood test measurements will be taken at the time of admission or later, as per the treating physician's discretion, and will be completed as per routine laboratory investigations:
2. Serum bilirubin
3. Blood counts
4. Reticulocyte counts
5. G6PD status
6. Blood group of mother and baby
7. Antibody titres
8. Coombs test results

Secondary outcome measures
Linear correlation between ETCOc values and the degree of hemolysis, as assessed using reticulocyte counts

Overall study start date
07/03/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Born or admitted in KK Women's and Children's Hospital
2. Gestational age of 35 weeks or more
3. Birth weight of 2000 g or more
4. Presence of jaundice and requiring phototherapy or presence of blood group incompatibility /G6PD deficiency

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Maternal history of smoking
2. Neonates requiring respiratory support

Date of first enrolment
09/07/2018

Date of final enrolment
22/11/2018

Locations

Countries of recruitment
Singapore

Study participating centre
KK Women's and Children's Hospital
100 Bukit Timah Road, Singapore-229899
Singapore
229899

Sponsor information

Organisation
United Italian Trading Corporation (PTE) LTD

Sponsor details
28 Tai Seng Street
06-01 Sakae Building
Singapore
Singapore
534106

Sponsor type
Industry

Funder(s)

Funder type
Not defined

Funder Name
Department of Nepnatology, KK Women's and Children's Hospital, Singapore

Results and Publications

Publication and dissemination plan
Publication plan will be made after the final results are available.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	15/02/2021	Yes	No