

Breath carbon monoxide measurement in jaundiced newborns

Submission date 02/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/07/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/02/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Dr Ashwani Bhatia Bhatia

Contact details

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229899

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 Nephrology, 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