

# Breath carbon monoxide measurement in jaundiced newborns

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<b>Registration date</b> 20/07/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/02/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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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Singapore

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?
<a href="#">Results article</a>	results	01/01/2020	15/02/2021	Yes	No