

# Simultaneous non-invasive measurement of breathing and ductal flow at birth

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To investigate the effect of breathing on ductus arteriosus flow by gathering simultaneous hemodynamic and respiratory data in healthy term infants

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON38732

### Source

ToetsingOnline

### Brief title

SIMBAD study

## Condition

- Other condition

### Synonym

breathing, Ductus arteriosus

### Health condition

hemodynamische en respiratoire transitie bij geboorte

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** ductus arteriosus, hemodynamic transition, newborn, respiratory transition

## Outcome measures

### Primary outcome

Changes in ductal flow during the measured time intervals (between 2-, 5- and 10 minutes) due to the effect of breathing.

### Secondary outcome

Correlation of ductal bloodflow with respiration

## Study description

### Background summary

The transition to extra uterine life at birth represents one of the greatest physiologic challenges that most humans encounter and begins with lung aeration and the onset of air-breathing. Liquid that fills the airways before birth must be cleared immediately after birth to allow the entry of air, the recruitment of a functional residual capacity (FRC), and the onset of pulmonary gas exchange. These processes initiate respiratory and cardiovascular responses in the newborn that underpin the successful transition from fetal to postnatal life. The processes include a large increase in pulmonary blood flow, closure of vascular shunts to separate the systemic and pulmonary circulations, the onset of sustained regular breathing, and increased blood oxygenation.

Much of our knowledge of the hemodynamic and respiratory transition at birth is based on animal studies. Data in human newborns are sparse because of the invasive techniques that would be necessary to obtain them. Recently we have shown that it is feasible to perform echocardiographic measurements immediately after birth. One of our findings was that a large inspiratory effort causes an immediate and significant increase in left to right shunt through the ductus arteriosus. The increase in left to right shunt may play an important role in compensating the up to 50% reduced systemic venous return to the right ventricle which takes place after clamping the umbilical cord. Furthermore, the shunt will lead to an increased blood flow to the pulmonary vasculature at birth, thereby increasing preload to the left ventricle. Thus, the change in ductus arteriosus blood flow will have direct influence on both the respiratory and hemodynamic transition shortly after birth.

A better understanding of this physiological adaptation is essential when attempting to understand problems associated with circulation in the immediate newborn period and to develop strategies to support transition.

### **Study objective**

To investigate the effect of breathing on ductus arteriosus flow by gathering simultaneous hemodynamic and respiratory data in healthy term infants

### **Study design**

Prospective observational study

### **Study burden and risks**

none

## **Contacts**

### **Public**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2300 RC  
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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

**Age**

Children (2-11 years)

**Inclusion criteria**

Healthy term (\* 37 weeks of gestation) infants delivered by elective caesarean section.

**Exclusion criteria**

Infants with suspected malformation and all infants with need of any respiratory support or additional inspired oxygen during transition are excluded.

**Study design****Design**

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

**Recruitment**

NL

Recruitment status: Recruiting

Start date (anticipated): 01-12-2013

Enrollment: 17

Type: Actual

**Ethics review**

Approved WMO

Date: 26-06-2013

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL43119.058.13