

# Lung ultrasound to monitor respiratory function in extremely preterm neonates

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<b>Registration date</b> 11/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/12/2023	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lung ultrasound is a radiation-free, non-invasive and simple technique commonly used in critical care medicine. The use of lung ultrasound is associated with many advantages in patients with acute respiratory failure and does not present any safety risk, unlike X-rays. Thus, these characteristics identify lung ultrasound as a suitable technique to follow-up preterm neonates. In fact, these small patients are hospitalized for several weeks needing some types of respiratory support while they grow up. This situation is called "chronic respiratory insufficiency of prematurity", may last for long time and may evolve into bronchopulmonary dysplasia (BPD). This latter is a chronic prematurity-related disease which is diagnosed at 36 weeks post-menstrual age, that is, several weeks after the birth of an extremely preterm infant. BPD represents an important clinical outcome but is only diagnosed according to some clinical criteria (such as need for oxygen or other respiratory support) accumulated overtime (after the first days of life until the 36 weeks' time-point). To date there is no diagnostic tool available to diagnose BPD.

Lung ultrasound holds the potential to be a simple, non-invasive and useful tool: 1) to monitor how neonates are doing, and 2) to eventually predict the BPD occurrence. The main study aim is to verify that lung ultrasound can successfully achieve these two results.

### Who can participate?

Neonates with gestational age  $\leq 30+6$  weeks

### What does the study involve?

Extremely preterm neonates fulfilling inclusion criteria will be included and will receive a lung ultrasound examination every 7-14 days during their hospitalization. The images obtained will be used to understand the respiratory function and eventually predict the occurrence of BPD. The images will be recorded together with some basic data usually registered in patients' files (amount of oxygen, type of respiratory support) and demographics.

### What are the possible benefits and risks of participating?

This study is totally free of risk for recruited patients, since lung ultrasound is a non-invasive technique, only requiring few minutes, and already used in clinical care. Conversely, the study will be useful for many patients worldwide if the usefulness of lung ultrasound, in respect to the

two main study aims, will be demonstrated: this will help diffusing the technique and improving the care of preterm infants worldwide.

Where is the study run from?

Paris Saclay University Hospital, "A.Béclère" Medical center (France)

When is the study starting and how long is it expected to run for?

January 2017 to September 2019

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof. Daniele De Luca, dm.deluca@icloud.com

## Contact information

### Type(s)

Scientific

### Contact name

Prof Daniele De Luca

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

Nil known

# Study information

## Scientific Title

Lung ultrasound to follow evolution of chronic respiratory insufficiency and predict bronchopulmonary dysplasia in extremely preterm neonates: a multicenter, prospective, pragmatic, observational cohort study

## Acronym

LUSTRE (Lung UltraSound To pReTerm nEonates)

## Study objectives

1. Semi-quantitative lung ultrasound through the calculation of lung ultrasound scores is useful to monitor respiratory function in neonates with chronic pulmonary insufficiency of prematurity (CPIP).
2. Semi-quantitative lung ultrasound through the calculation of lung ultrasound scores is useful to predict bronchopulmonary dysplasia (BPD) occurrence.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 10/03/2017, Commission d'Ethique de la Société de Réanimation de Langue Française (48, avenue Claude Vellefaux – 75010 Paris, France; +33 (0)1 45 86 74 00; secretariat@srlf.org), ref: SRLF16-58

## Study design

Observational multicenter prospective pragmatic cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

No participant information sheet available

## Health condition(s) or problem(s) studied

Chronic pulmonary insufficiency of prematurity (CPIP) and bronchopulmonary dysplasia (BPD)

## Interventions

Lung ultrasound performed serially every 7 - 14 days in extremely preterm neonates with CPIP and hospitalised in neonatal intensive care units. Based on lung ultrasound findings a lung ultrasound score will be calculated as published by Brat R. JAMA Pediatr 2015. An extended lung ultrasound score will also be calculated considering ultrasound findings in posterior lung zones.

### **Intervention Type**

Other

### **Primary outcome measure**

1. Lung aeration in neonates with CPIP using the correlation between lung ultrasound scores (calculated as published by Brat R. JAMA Pediatr 2015) and gas exchange measures performed every 7 - 14 days
2. Bronchopulmonary dysplasia (BPD) at 36 weeks post-menstrual age measured according to clinical criteria (such as need for oxygen or other respiratory support)

### **Secondary outcome measures**

None

### **Overall study start date**

01/01/2017

### **Completion date**

01/09/2019

## **Eligibility**

### **Key inclusion criteria**

Inborn neonates with gestational age  $\leq 30+6$  weeks

### **Participant type(s)**

Patient

### **Age group**

Neonate

### **Lower age limit**

0 Days

### **Sex**

Both

### **Target number of participants**

at least 100 (convenience sample size)

### **Total final enrolment**

147

### **Key exclusion criteria**

1. Complex congenital malformations
2. Chromosomal abnormalities
3. Pulmonary hypoplasia
4. Congenital anomalies of surfactant proteins or any other suspected congenital lung disorders

**Date of first enrolment**

01/09/2017

**Date of final enrolment**

30/06/2019

## **Locations**

**Countries of recruitment**

France

Italy

**Study participating centre**

**Paris Saclay University Hospital, "A.Béclère" Medical center**

157 rue de la Porte de Trivaux

Clamart

France

92140

**Study participating centre**

**"G.Salesi" Women's and Children Hospital**

via Filippo Corridoni 11

Ancona

Italy

60123

**Study participating centre**

**Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico**

Via della Commenda 12

Milano

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20122

**Study participating centre**

**Policlinico Universitario di Padova**

Via Niccolo Giustiniani 2

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35128

**Study participating centre**  
**AOU "Federico II"**  
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## Sponsor information

**Organisation**  
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**Sponsor type**  
Hospital/treatment centre

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

## Publication and dissemination plan

Results will be partially presented at Pediatric Academic Society Meeting in the US and at the meeting of the European Society for Pediatric and Neonatal Intensive Care (ESPNIC) in Europe.. Then results will be published in one or more article(s).

## Intention to publish date

31/12/2020

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>		11/05/2020	12/05/2020	No	No
<a href="#">Results article</a>		01/06/2021	27/12/2023	Yes	No