

# Assessing the likelihood of needing a substance called surfactant for newborns born near their expected delivery date using lung ultrasound

<b>Submission date</b> 23/12/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/01/2024	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Lung ultrasound is a non-invasive, easy and quick technique that is being increasingly used in the clinical practice worldwide. It has been proven to be very accurate to evaluate the severity of respiratory failure and the need for surfactant replacement in preterm and extremely preterm neonates. Nonetheless, it is unclear if it is equally accurate and useful to predict surfactant need in late preterm and term neonates, as they may be affected by different types of respiratory failure.

### Who can participate?

Late preterm and term (i.e. beyond 34 weeks' gestation) may be enrolled in this study

### What does the study involve?

The study is performed within the usual routine care in the participating centres. The results of lung ultrasound will be collected together with the data registered during the standard monitoring of these patients.

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

Participation in the study will be useful and bring benefits on a larger scale since it may significantly improve the management of these patients.

No test is performed solely for study purposes and there is no risk whatsoever for the patients. On the contrary, lung ultrasound is non-invasive and is already used in clinical practice to visualise the lungs and have more insights about the respiratory disorder.

### Where is the study run from?

APHP-Paris Saclay University DMU2 (France)

Università degli Studi di Padova (Italy)-Dpt di Pediatria

NICU, Hospital Universitario "Puerta del Mar" Cadiz (Spain)

NICU, Dept of Pediatrics, Stanford University (Palo Alto-CA, USA)

NICU, Federico II University Napoli (Italy)

When is the study starting and how long is it expected to run for?  
June 2021 to December 2023

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Prof. Daniele De Luca (MD, PhD), [daniele.deluca@aphp.fr](mailto:daniele.deluca@aphp.fr)

## Contact information

**Type(s)**  
Public, Scientific, Principal investigator

**Contact name**  
Prof Daniele De Luca

**ORCID ID**  
<https://orcid.org/0000-0002-3846-4834>

**Contact details**  
Hospital A.Beclere  
Clamart  
France  
92140  
+33 145374837  
[daniele.deluca@aphp.fr](mailto:daniele.deluca@aphp.fr)

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Quantitative lung ultrasound to predict surfactant need in late preterm and term neonates with respiratory failure

**Acronym**  
ULTRAS

**Study objectives**

A previously validated and well known neonatal lung ultrasound score can predict the surfactant need in late preterm and term neonates with respiratory failure in the first 72h of life with at least the same accuracy shown in preterm neonates.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 30/06/2022, Comitato Etico per la Sperimentazione Clinica della Provincia di Padova (via Giustiniani 1, Padova, 35128, Italy; +39 498211435; luca.bonadies@unipd.it), ref: 5495/AO/22

### **Study design**

Prospective observational pragmatic non-invasive international multi-center cohort study

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

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

Surfactant need in late preterm and term infants

### **Interventions**

Calculation of the lung ultrasound scores performed upon NICU admission and before surfactant administration (if any) together with the consideration of data issued of vital monitoring. Ultrasound and monitoring are performed within the routine clinical care in the participating centers (so that no test is performed solely for study purposes) and the study is pragmatically "nested" within clinical care.

### **Intervention Type**

Other

### **Primary outcome(s)**

Upon NICU admission and before surfactant administration (if any):

1. Diagnostic accuracy measures (area under the ROC curve and derived accuracy variables). For these outcomes, lung ultrasound scores and need for surfactant replacement will be collected (i. e.: this will allow the raw calculation of true and false positives and negatives).
2. Additionally demographics, clinical and monitoring variables usually registered during routine care will be collected.

### **Key secondary outcome(s)**

Oxygenation metrics measured with usual vital monitoring available in each center and its relationship with lung ultrasound score measured using patient records upon NICU admission and before surfactant administration (if any)

### **Completion date**

20/12/2023

## **Eligibility**

**Key inclusion criteria**

All late preterm and term ( $\geq 34$  weeks' gestation) neonates admitted to the NICU in the first 72 h of life with respiratory failure

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

157

**Key exclusion criteria**

1. Major congenital malformations or chromosomopathies
2. Airleaks preventing a comprehensive lung ultrasound examination
3. Early onset sepsis and hemodynamic instability (defined as need for any inotrope)
4. Congenital surfactant anomalies
5. Pulmonary hypoplasia or congenital lung malformations
6. PPHN
7. Need for surgery in the first week of life

**Date of first enrolment**

01/12/2022

**Date of final enrolment**

20/12/2023

**Locations****Countries of recruitment**

France

Italy

Spain

United States of America

**Study participating centre**

APHP-Paris Saclay University, "Beclere" medical center

157 rue de la Porte de Trivaux

Clamart  
France  
92140

**Study participating centre**  
**Azienda Ospedaliero-Universitaria di Padova**  
V.le Giustiniani 2  
Padova  
Italy  
35128

**Study participating centre**  
**Azienda Ospedaliero-Universitaria "Federico II"**  
Via Sergio Pansini, 5  
Napoli  
Italy  
80131

**Study participating centre**  
**Hospital Universitario Puerta del Mar**  
Avenida Ana de Viya 21  
Cadiz  
Spain  
11009

**Study participating centre**  
**Lucile Packard Children's Hospital - Stanford University**  
725 Welch Road, Palo Alto, CA  
Palo Alto (CA)  
United States of America  
94304

## **Sponsor information**

**Organisation**  
APHP-Paris Saclay University DMU2

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The whole dataset used in the study will be available from the study coordinator (Prof. Daniele De Luca (MD, PhD) - [daniele.deluca@aphp.fr](mailto:daniele.deluca@aphp.fr)) upon reasonable request with clear aims and respecting privacy regulation.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/05/2024	14/06/2024	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>			28/12/2023	No	No