

Lung ultrasound to monitor respiratory function in extremely preterm neonates

Submission date 05/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/12/2023	Condition category 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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Additional identifiers

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 Reanimation de Langue Francaise (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

Study type(s)

Diagnostic

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(s)

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)

Key secondary outcome(s)

None

Completion date

01/09/2019

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Lower age limit

0 days

Sex

All

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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Study participating centre
Policlinico Universitario di Padova
Via Niccolo Giustiniani 2
Padova
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Study participating centre
AOU "Federico II"
via Sergio Pansini 5
Napoli
Italy
80131

Sponsor information

Organisation
GHU Paris Saclay

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

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?
Results article		01/06/2021	27/12/2023	Yes	No
Protocol file		11/05/2020	12/05/2020	No	No