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Lung ultrasound to monitor respiratory function in extremely preterm neonates

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
11/05/2020

Overall study status
Completed

Last Edited
27/12/2023

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 <=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

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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 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

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 <=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
Italy
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Study participating centre
Policlinico Universitario di Padova
Via Niccolo Giustiniani 2

Padova
Italy
35128

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AOU "Federico II"
via Sergio Pansini 5
Napoli
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Sponsor information

Organisation
GHU Paris Saclay

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