

A study about the relationship between lung ultrasound findings and inflammatory markers in neonates with respiratory failure

Submission date 02/10/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/10/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/03/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Ultrasound is a non-invasive technique that uses a device placed against the skin to emit and receive high-frequency sound waves to create an image of part of the inside of the body, for example, to monitor developments during pregnancy. Lung ultrasound is a useful medical technique that can be used to evaluate the appearance and function of the lungs. This is needed for newborns with breathing (respiratory) difficulties. In these newborns, consolidations may be seen on ultrasound. These are areas of the lungs that should be filled with air but are instead filled with a liquid or a solid.

The aim of this study is to demonstrate that the size and/or number of consolidations in newborns with respiratory failure are related to the patients' inflammatory status. Inflammatory marker levels will be raised during infection and are commonly measured in routine clinical care of newborns. There are many causes for newborns to develop respiratory failure and it is important to be able to make a correct diagnosis in order to treat them in the appropriate way. It is hoped that this study will help doctors to decide whether the cause of respiratory failure is an infection or not.

Who can participate?

Newborns (aged 0-4 weeks) admitted to a neonatal intensive care unit with any type of respiratory failure and having consolidations at the lung ultrasound.

What does the study involve?

The study involves a lung ultrasound scan of the newborn. This is a non-invasive diagnostic procedure that is already performed within routine care in the participating centres. The study also involves the collection of clinical data and the value of inflammatory markers that will be measured during routine care.

What are the possible benefits and risks of participating?

It is hoped that the results of this study will allow us to better understand and interpret ultrasound signs, therefore allowing doctors to confirm whether respiratory failure in newborns

has been caused by an infection. This will help to provide a more accurate diagnosis and to provide fast and effective care.

There are no risks associated with this study. There will be no intervention beyond routine clinical care and there will only be a simple data collection during this care. Participants in the study will not receive any changes to their treatment. Collected data will be totally anonymous and the study will respect all relevant privacy regulations. Good clinical research practices will always be respected.

Where is the study run from?

Neonatal Intensive Care Units in France, Italy, and Spain with particular expertise in lung ultrasound using this technique within their common routine clinical care.

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

From January 2021 to December 2022

Who is funding the study?

Investigator-initiated and funded

Who is the main contact?

Prof. Daniele De Luca

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Contact information

Type(s)

Public, Scientific

Contact name

Prof Daniele De Luca

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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 features and inflammation in NICU-admitted neonates (UNION)

Acronym

UNION

Study objectives

Size or aspects of consolidations at the lung ultrasound may help to distinguish their infectious or non-infectious origin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/04/2021, Critical Care French Ethical Commission (SRLF Commission d'Ethique, 48, avenue Claude Vellefaux, 75010 Paris; +33 (0)1 45 86 74 00; secretariat@srlf.org), ref: 21/33

Study design

Prospective observational 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

Refined diagnosis of different types of neonatal respiratory failure

Interventions

Point-of-care lung ultrasound at the bedside will be performed within the routine clinical care of the neonate. Details of the technique are available in Raimondi F, Yousef N, Migliaro F, Capasso L, De Luca D. Point-of-care lung ultrasound in neonatology: classification into descriptive and functional applications. *Pediatr Res*. 2018 Jul 20;1–8. doi: 10.1038/s41390-018-0114-9.

Intervention Type

Other

Primary outcome measure

Integrated clinical diagnosis obtained using clinical and anamnestic data, together with following, collected within routine care:

1. Lung ultrasound score calculated using point-of-care lung ultrasound
2. Maximal size from the pleura to their inferior margin of consolidation measured using point-of-care lung ultrasound
3. Inflammatory biomarker (such as procalcitonin, C-reactive protein, or others) levels measured using clinical routine blood samples

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2021

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Neonates presenting with respiratory failure
2. Requiring any type of respiratory support including O2 supplementation, HHHFNC, CPAP, different types of NIV or invasive ventilation, or ECMO
3. ≥ 1 consolidation on lung ultrasound performed during clinical care. Consolidation is defined according to classical lung ultrasound semiology as the presence of echo-poor or tissue-like echotexture originating from the pleural line area with irregular borders, which may also have mixed hypoechogenic and hyperechogenic spots representing air bronchograms. In order to search for consolidations, a lung ultrasound exam must be complete and all chest areas (including posterior ones) should be scanned.

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

Key exclusion criteria

1. Major congenital malformations
2. Congenital lung anomalies
3. Cytogenetic anomalies
4. Need for thoracic surgery
5. Massive air leaks preventing a detailed evaluation of lung parenchyma

Date of first enrolment

15/04/2021

Date of final enrolment

31/12/2022

Locations**Countries of recruitment**

France

Italy

Spain

Study participating centre

Paris Saclay University Hospitals, "A. Beclere" Medical Center

157 rue de la Porte de Trivaux

Clamart

Paris

France

92140

Study participating centre

University of Milan Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico

Department of Clinical Sciences and Community Health

Via Della Commenda 12

Milano

Italy

20122

Study participating centre

Università "Federico II" di Napoli

Division of Neonatology, Section of Pediatrics Dept of Translational Medical Sciences

Via Sergio Pansini

Napoli

Italy
80131

Study participating centre

Ospedale Universitario di Padova

Divisione di neonatologia, Dipartimento Salute della Dona e del Bambino
Via Nicolò Giustiniani 2
Padova
Italy
35128

Study participating centre

Hospital Universitario Puerta del Mar

Department of Neonatology (NICU)
Avenida Ana de Viya 21
Cadiz
Spain
11009

Sponsor information

Organisation

Hôpital Antoine-Béclère

Sponsor details

APHP- Departement Medico-Universitaire n.2 "Santé des Femmes et Nouveau-nés"
157 rue de la Porte de Trivaux
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Sponsor type

Hospital/treatment centre

Website

<http://www.aphp.fr/contenu/hopital-antoine-beclere-1>

ROR

<https://ror.org/04sb8a726>

Funder(s)

Funder type

Other

Funder Name

Investigator-initiated and self funded

Results and Publications

Publication and dissemination plan

The study results will be presented at the main international congress in the field of neonatal critical care (for ex.: ESPNIC, PAS) and published in one or more articles in top flag journals. ICMJE criteria for authorship and STROBE guidelines will be applied.

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The anonymous dataset generated and analysed during the study will be available upon reasonable request from the PI Prof. Daniele De Luca (daniele.deluca@aphp.fr). Availability may be subject to administrative approval according to privacy regulations, depending on the country from which the request originates.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/02/2024	29/02/2024	Yes	No