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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

Registration date
05/10/2021

Overall study status
Completed

Last Edited
01/03/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
daniele.deluca@aphp.fr

Contact information

Type(s)
Public, Scientific

Contact name
Prof Daniele De Luca

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

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
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80131

Study participating centre
Ospedale Universitario di Padova
Divisione di neonatologia, Dipartimento Salute della Dona e del Bambino
Via Nicolò Giustiniani 2
Padova
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35128

Study participating centre

Hospital Universitario Puerta del Mar
Department of Neonatology (NICU)
Avenida Ana de Viya 21
Cadiz
Spain
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Sponsor information

Organisation
Hôpital Antoine-Béclère

ROR
https://ror.org/04sb8a726

Funder(s)

Funder type
Other

Funder Name
Investigator-initiatd and self funded

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes