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

Submission date
23/12/2023

Recruitment status
No longer recruiting

Registration date
02/01/2024

Overall study status
Completed

Last Edited
14/06/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[X] Results
[_] 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 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)
Universita 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

Contact information

Type(s)
Public, Scientific, Principal Investigator

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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
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/06/2021

Completion date
20/12/2023

Eligibility

Key inclusion criteria
All late preterm and term (>=34 weeks' gestation) neonates admitted to the NICU in the first 72 h of life with respiratory failure

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
142

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

Sponsor details
157 rue de la Porte de Trivaux
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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
Planned publication in high-impact journals and partial data presentation at the main North-America and European NICU congresses

Intention to publish date
01/06/2024

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) 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?
Statistical Analysis Plan			28/12/2023	No	No
Results article		01/05/2024	14/06/2024	Yes	No