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Lung ultrasound score to predict the need of second dose of surfactant and respiratory outcomes in neonatal respiratory distress syndrome

Submission date
10/07/2025

Recruitment status
No longer recruiting

Registration date
19/09/2025

Overall study status
Completed

Last Edited
19/09/2025

Condition category
Neonatal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims:
Newborn respiratory distress syndrome (NRDS) happens when a baby's lungs are not fully developed and cannot provide enough oxygen, causing breathing difficulties. NRDS usually occurs when the baby's lungs have not produced enough surfactant. Lung ultrasound score (LUS) calculated in the first 2 hours of life can reliably guide surfactant replacement in newborns with respiratory distress syndrome. This study explores the role of the early LUS in predicting the need for a second dose of surfactant.

Who can participate?
Premature newborns with respiratory distress, born between 25- 33 weeks of gestational age

What does the study involve?
Preterm newborns stabilized with respiratory distress according to the local NICU protocol with any kind of respiratory support were enrolled within 120 minutes of birth and LUS was calculated. Surfactant administration is decided by an attending neonatologist, unaware of the results of the LUS, based on radiographic and clinical signs.
The local investigator recorded the subsequent respiratory support provided and important clinical outcomes until discharge. The primary aim of the study is to evaluate the early LUS performance as a predictor of the second surfactant dose administration by an attending physician.

What are the possible benefits and risks of participating?
The possible benefit is to receive an early and individualized administration of the second surfactant dose before further deterioration of the newborn's clinical condition and potentially with better respiratory outcomes. No risks are expected because lung ultrasound is a non-invasive and radiation-free tool.

Where is the study run from?
University Federico II (Italy)

When is the study starting and how long is it expected to run for?
February 2022 to May 2025

Who is funding the study?
University Federico II (Italy)

Who is the main contact?
Prof. Francesco Raimondi, raimondi@unina.it

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
001

Study information

Scientific Title
An early lung ultrasound score predicts the need for surfactant retreatment and long-term outcomes in neonatal respiratory distress syndrome

Acronym

LUSecond

Study objectives
To evaluate the lung ultrasound score (LUS) performance as a predictor of the second surfactant dose administration by a masked attending physician. An early LUS, done in the first 2 hours of life, will be considered.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/02/2022, Comitato Etico Universita Federico II (Pansini 5, Naples, 80131, Italy; +39 (0)81 7462596; segreteria@comitatoeticocampania3.it), ref: 386/21

Study design
Observational prospective study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Neonatal respiratory distress syndrome

Interventions
Preterm neonates stabilized according to the local NICU protocol and managed with any kind of respiratory support are enrolled within 120 minutes of birth when important prenatal variables were recorded. During this time, the attending neonatologist, unaware of the purpose of the study, decides on the initial stabilization with either CPAP or nasal intermittent ventilation or mechanical ventilation according to the clinical condition.

An investigator who was not involved in the clinical care records the respiratory support mode and level and oxygenation indices. The investigator also performed a lung ultrasound scan as previously described using three predefined ultrasound views (middle clavicular, anterior axillary and posterior axillary lines) on each side.

Intervention Type
Other

Primary outcome(s)
Early LUS performance as a predictor of the second surfactant dose administration by a masked attending physician. LUS is performed in the first 2 hours of life using the Brat score.

Key secondary outcome(s))
Main respiratory outcomes in relation to the need for a second surfactant dose, measured by evaluating oxygen indices and the respiratory technique used at stabilization.
Bronchopulmonary dysplasia (according to the Jensen definition) and the number of deaths will be registered at discharge.

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Premature neonates with respiratory distress syndrome (RDS)
2. Born between 25- 33 weeks of gestational age calculated from the first day of the last menstrual period
3. Studied before their first surfactant dose

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 days

Upper age limit
1 days

Sex
All

Total final enrolment
225

Key exclusion criteria
1. Lack of parental consent
2. Major congenital malformations
3. Surfactant administration before lung ultrasound

Date of first enrolment
01/03/2022

Date of final enrolment
31/05/2025

Locations

Countries of recruitment
Italy

Study participating centre
University Federico II
Via Pansini 5
Napoli
Italy
80131

Sponsor information

Organisation
University of Naples Federico II

ROR
https://ror.org/05290cv24

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Napoli Federico II

Alternative Name(s)
University of Naples Federico II, University of Naples, Federico II University of Naples, Università di Napoli, Università di Napoli Federico II, UNINA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The dataset of the current study will be available upon reasonable request to Prof. Francesco Raimondi (raimondi@unina.it)

IPD sharing plan summary

Available on request