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Lung ultrasound score and variable respiratory support

Submission date	Recruitment status	[_] Prospectively registered
07/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/06/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2025	Respiratory	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Lung ultrasound predicts surfactant administration in neonates with moderate respiratory distress syndrome stabilized on continuous positive airway pressure (CPAP), but whether this is true for more critical infants is unknown. The objective of this study is to assess whether lung ultrasound may also predict surfactant replacement in infants on different respiratory support over a wide range of mean airway pressure.

Who can participate?
Neonates with respiratory distress in the first 2 hours of life stabilized with different techniques of respiratory support.

What does the study involve?
This study is a pragmatic, observational study set in Italian and Spanish neonatal intensive care units

What are the possible benefits and risks of participating?
It is hoped that future patients will benefit from the findings that lung ultrasound allows an early and targeted surfactant replacement.
Neonates participating in the study have no possible risks because they will not undergo new procedures because of the study itself. It is an observational study without interventions on patients.

Where is the study run from?
University of Naples Federico II (Italy). Neonatology Section

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

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

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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
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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
Does lung ultrasound predict surfactant administration in neonates with respiratory distress stabilized with different support techniques? An international, pragmatic study

Acronym
LUSVENT

Study objectives
Lung ultrasound accurately predicts surfactant administration in neonates with respiratory distress syndrome stabilized on CPAP. However, whether this is true for more critical infants

stabilized with non-invasive or invasive ventilation is unknown. The objective of the study is to assess whether lung ultrasound may also predict surfactant replacement in infants on different respiratory support over a wide range of mean airway pressure

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/02/2022, Comitato Etico Universita' Federico II (Via Pansini 5, Napoli, 80131, Italy; +39 081 746 2596; segreteria@comitatoeticocampania3.it), ref: 386/21

Study design
Observational prospective multicenter international cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Accuracy of lung ultrasound score to predict surfactant administration in neonates with respiratory distress stabilized with different support techniques

Interventions
The lung ultrasound score will be obtained for three groups of neonates with respiratory distress, stabilized on continuous positive airway pressure (CPAP), non-invasive ventilation and invasive ventilation within 2 hours of life. The result of the score will be carefully concealed from the attending physician evaluating the later need for surfactant administration. The predictive accuracy for surfactant of the lung ultrasound score alone or with non-invasive variables will be investigated according to the different respiratory support techniques. After the lung ultrasound at the enrolment, participants will receive a lung ultrasound at 7 days of life and 36 weeks of gestational age. Data relating to general prenatal and neonatal characteristics, respiratory support, oxygen supplementation, onset of complications of prematurity will be monitored and collected until discharge from NICU.

Intervention Type
Other

Primary outcome(s)
The predictive accuracy of the lung ultrasound score of surfactant therapy measured using the Brat Score in the first 2 hours of life

Key secondary outcome(s))
1. The prognostic accuracy for surfactant administration measured using data collected from patient medical record in the whole population and the three groups of the following individual predictors at enrolment, 7 days and 36 weeks of gestational age:
1.1. SatO2/ FiO2
1.2. FiO2>0.3
1.3. OSI index
2. The prognostic accuracy for surfactant administration in the whole population of a previously

developed logistic regression model based on lung ultrasound according to the Brat Score, gestational age, with/without oxygenation indexes evaluated at the enrolment.
3. The clinical trajectory and outcome of infants stabilized with techniques other than CPAP evaluating the progression of lung ultrasound score and oxygenation indexes at enrolment, 7 days and 36 weeks of gestational age and evaluating need and duration of oxygen and respiratory support, diagnosis of bronchopulmonary dysplasia and death at the end of NICU staying.

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Premature neonates with respiratory distress
3. Any gestational age
2. Enrolled within 2 hours of birth
3. Before the administration of the first surfactant dose

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
1 days

Upper age limit
1 days

Sex
All

Key exclusion criteria
1. Infants with major congenital malformations
2. Those who had already been given surfactant

Date of first enrolment
01/05/2024

Date of final enrolment
01/05/2025

Locations

Countries of recruitment

Italy

Spain

Study participating centre
Università Federico II. Neonatologia
Via Pansini 5
Napoli
Italy
80131

Study participating centre
Sección Neonatología Hospital Universitario Puerta del Mar
Avenida Ana de Viya, 21
Cadiz
Spain
11009

Study participating centre
Neonatologia e Terapia Intensiva Neonatale ASST - Grande Ospedale Metropolitano Niguarda
Piazza Ospedale Maggiore, 3
Milano
Italy
20162

Study participating centre
Pediatric Intensive Care Unit. Pediatric Service Germans Trias i Pujol University Hospital
Ctra. de Canyet, s/n
Badalona
Spain
08916

Study participating centre
Neonatology Hospital General Universitario Gregorio Marañón
O'Donnell 48
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Spain
28009

Study participating centre
Ospedale dei Bambini "V.Buzzi" ASST-FBF-Sacco
Via Castelvetro, 32
milano
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Study participating centre
Neonatology. Padova University Hospital
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Study participating centre
Policlinico Universitario Agostino Gemelli
Largo Agostino Gemelli 8
Roma
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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 datasets generated during and/or analysed during the current study are/will be available upon request from Prof Francesco Raimondi, raimondi@unina.it (Italy) from May 2026.

• The type of data that will be shared: all data registered in the Excel database of the study
• Timing for availability: 5 years from publication of study
• Whether consent from participants was required and obtained: consent required and obtained (study in progress)
• Comments on data anonymization: data will be shared completely anonymised
• Any ethical or legal restrictions: no restriction
• Any additional comments: Data will be available upon reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes