

Lung ultrasound score and variable respiratory support

Submission date 07/03/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/06/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2025	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Prof Francesco Raimondi

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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

Madrid

Spain

28009

Study participating centre**Ospedale dei Bambini "V.Buzzi" ASST-FBF-Sacco**

Via Castelvetro, 32

milano

Italy

20154

Study participating centre**Neonatology. Padova University Hospital**

via Giustiniani 3

Padova

Italy

35128

Study participating centre**Policlinico Universitario Agostino Gemelli**

Largo Agostino Gemelli 8

Roma

Italy

00136

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