

Understanding the development of broncho-pulmonary dysplasia (BPD) in preterm infants: mechanisms and different forms of BPD

Submission date 16/08/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2025	Overall study status Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/08/2025	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

Some babies born very early (prematurely) can develop a serious lung condition called broncho-pulmonary dysplasia (BPD). This condition can affect their growth, brain development, and heart and lung health later in life. Doctors and researchers believe there may be different types of BPD, each developing in its own way, but we don't yet fully understand how or why. This study aims to learn more about the different forms of BPD and how they develop, which could help improve care for these babies in the future.

Who can participate?

Any newborn baby born before 30 weeks of pregnancy (gestational age) can take part in the study.

What does the study involve?

The study does not involve any extra tests or procedures. It simply uses information that is already being collected as part of the baby's normal hospital care. This includes things like data from breathing support machines, vital signs monitoring, and routine lung scans.

What are the possible benefits and risks of participating?

There are no risks to taking part in the study because nothing about the baby's care will change. The information collected could help doctors better understand BPD and eventually lead to more personalised treatments for babies with different types of the condition.

Where is the study run from?

The study is being carried out in several specialist newborn intensive care units and research centres across Europe.

When is the study starting and how long is it expected to run for?

The study is already underway and is expected to continue until sometime in 2026, depending on how many babies are enrolled.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Almudena Alonso-Ojembarrena, almudena.alonso.sspa@juntadeandalucia.es

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Almudena Alonso-Ojembarrena

Contact details

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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

Pathophysiology phenotypes in infants developing BPD

Acronym

PATH-BPD

Study objectives

Clarifying pathophysiology and biology phenotypes of BPD

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/07/2023, Junta de Andalucía - Comité de Ética de Investigación de Cádiz (Avenida Ana de Viva, 12- 11009 Cádiz, Cádiz, 11009, Spain; +34 950002100; ceic.hpm.sspa@juntadeandalucia.es), ref: TFG-LUSNEO1-2023

Study design

Observational prospective multi-center non-invasive pragmatic study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Broncho-pulmonary dysplasia

Interventions

Analysis of clinical, imaging physiological and vital data routinely collected during NICU care.

Intervention Type

Other

Primary outcome measure

Gas exchange metrics, lung aeration, vital functions, respiratory support and lung mechanics data are registered at 10, 21 and 28 days of life as well as at 34 and 36 weeks post-conceptual age. Measurements are performed with commonly used techniques such as transcutaneous blood gas monitoring, blood gas analyses, quantitative lung ultrasound, electrical cardiometry, pulse oximetry and the measurements shown by mechanical ventilators screens, as per clinical routine

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/12/2023

Completion date

31/12/2026

Eligibility

Key inclusion criteria

Preterm neonates (GA \leq 30 weeks)

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

A convenience sample size of approximately 300 participants is expected to be enrolled. However, since this is the first study on pathophysiological phenotypes of BPD, a formal sample size calculation is unfeasible

Key exclusion criteria

1. Complex malformations or chromosomal abnormalities
2. Congenital lung anomalies
3. Pneumothorax, pneumomediastinum or pleural effusion
4. Need for surgery
5. Severe hemodynamic instability (defined as any need for inotropes) at any time during the study

Date of first enrolment

01/01/2024

Date of final enrolment

31/12/2026

Locations

Countries of recruitment

France

Italy

Spain

Study participating centre

Hospital Puerta del Mar

Av. Ana de Viya, 21, 11009 Cádiz, Espana

Cádiz

Spain

11009

Study participating centre

Hopital "A.Beclere", APHP-Paris Saclay University

157 rue de la Poret de Trivaux 92140, Clamart (IDF), France

Clamart

France

92140

Study participating centre

Azienda Ospedaliero Universitaria di Padova

Via Nicolò Giustiniani, 2 - 35128 Padova, Italia

Padova

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35128

Sponsor information

Organisation

Hospital Universitario Puerta del Mar

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://hospitalpuertadelmar.com/>

ROR

<https://ror.org/040xzg562>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Study results will be diffused via one or several articles representing subsection of the study published in major international journals in the field of "critical care" or "pediatrics". Partial results will also be presented at the main conferences in the field (such as PAS, ATS or ESPNIC)

Intention to publish date

Individual participant data (IPD) sharing plan

The anonymised datasets generated and analysed will be available upon adequate request from researchers, respecting all relevant regulations. They will need to be requested to the main study contact (see above) and the establishment of a CDA may be needed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			19/08/2025	No	No