

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

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

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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 Vivia, 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

### **Study type(s)**

Other

### **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(s)**

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

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

31/12/2026

## **Eligibility**

### **Key inclusion criteria**

Preterm neonates (GA  $\leq$  30 weeks)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Neonate

**Sex**

All

**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

Cadiz

Spain

11009

**Study participating centre****Hopital "A.Beclere", APHP-Paris Saclay University**

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

Clamart

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**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

### ROR

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

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Statistical Analysis Plan</a>			19/08/2025	No	No