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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	[_] Prospectively registered [_] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/08/2025	**Overall study status** Ongoing	
Last Edited 19/08/2025	**Condition category** Respiratory	

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

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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 Andalucia - Comité ed Ética ed al Investigación de Cádiz (Avenida Ana deViva, 12- 11009 Cadiz, Cadiz, 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-conceptional age. Measurements are performed with commonly used techniques such as transcutaneous blood gas monitoring, blood gas analyses, quantitative lung ultrasound, electrical cardiometry, pulsoxymetry 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 <=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
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Study participating centre
Azienda Ospedaliero Universitaria di Padova
Via Nicolò Giustiniani, 2 - 35128 Padova, Italia
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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?
Statistical Analysis Plan			19/08/2025	No	No