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An international prospective cohort study on spontaneous pneumothorax

Submission date 22/10/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2025	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Spontaneous pneumothorax is a condition where air collects in the space around the lung, causing it to collapse. It most often affects teenagers and young adults, but can also occur later in life or in people with underlying lung conditions. Around the world, doctors use different approaches to manage this condition, including observation, aspiration (removal of air with a needle), chest drain placement, or surgery. This international study aims to understand how spontaneous pneumothorax is managed in different hospitals, how closely current practice follows international guidelines, and which factors affect outcomes and recurrence.

Who can participate?
Any patient of any sex or gender who is treated for spontaneous pneumothorax, either primary (in otherwise healthy lungs) or secondary (in people with known lung disease), at a participating hospital can take part.

What does the study involve?
The study collects information already recorded as part of normal hospital care, such as symptoms, imaging, treatment, and recovery. No extra tests or procedures are performed. Follow-up information will be collected at 30 days and 12 months to see how patients recover and whether the pneumothorax returns.

What are the possible benefits and risks of participating?
There are no direct risks or additional procedures beyond usual care. The information collected will help improve future treatment guidelines and patient outcomes around the world.

Where is the study run from?
The study is coordinated internationally by the GASP-OUT Steering Committee, with the lead centre based in Italy and collaboration from hospitals across multiple countries.

When is the study starting and how long is it expected to run for?
The study will begin recruitment in May 2026 and continue for six months, with follow-up for each patient lasting one year. The study is expected to finish in late 2027, with results published in 2028.

Who is funding the study?
This study is currently unfunded and is being conducted through international academic collaboration supported by participating hospitals and clinicians.

Who is the main contact?
Principal Investigator: Federica Pederiva, MD, PhD, Pediatric Surgery Unit, Azienda Ospedaliera Universitaria Integrata (AOUI) Verona, Verona, Italy, federica.pederiva@aovr.veneto.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Federica Pederiva

ORCID ID
https://orcid.org/0000-0002-2792-1550

Contact details
Azienda Ospedaliera Universitaria Integrata Verona
p.le A. Stefani, 1
Verona
Italy
37126
+39 0458127130
federica.pederiva@aovr.veneto.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
GASPOUT_study

Study information

Scientific Title
Global assessment of spontaneous pneumothorax: outcomes and treatment

Acronym
GASPOUT

Study objectives
This international prospective observational cohort study aims to evaluate global adherence to current evidence-based guidelines for the management of spontaneous pneumothorax in pediatric and adult patients, describe variations in practice across healthcare settings, and identify factors associated with outcomes and recurrence. The study seeks to generate real-

world data to inform future guideline development and optimize patient care pathways worldwide.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted, Comitato Etico Territoriale Area Sud-Ovest Veneto (territorial Ethics Committee of the South-West Veneto Area, Italy) (p.le A. Stefani, 1, Verona, 37126, Italy; +39 0458123236; comitatoetico@aovr.veneto.it), ref: Reference number not provided

Study design
Multicentre international prospective observational cohort study with 12-month longitudinal follow-up

Primary study design
Observational

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Spontaneous pneumothorax in pediatric and adult patients

Interventions
This is a multicentre, international, prospective observational cohort study enrolling consecutive patients presenting with spontaneous pneumothorax. Clinical, imaging, and management data will be collected using standardized case report forms, with follow-up at 30 days and 12 months to record recurrence, complications, and outcomes. No interventions or additional tests are mandated beyond routine clinical care.

Intervention Type
Other

Primary outcome(s)
Adherence to international evidence-based audit standards for the management of spontaneous pneumothorax, measured using a predefined checklist of guideline-derived criteria recorded at the time of index presentation and initial management.

Key secondary outcome(s))
1. Initial management strategy (observation, aspiration, drainage, ambulatory device, surgery) measured using standardized case report form (CRF) data at the time of index presentation.
2. Persistent air leak measured by clinical observation and documentation of ongoing bubbling >48–72 hours after intervention during index admission.
3. Complications (infection, bleeding, re-expansion pulmonary edema, device displacement) measured using CRF documentation during index admission and at 30-day follow-up.
4. Length of hospital stay measured in days from admission to discharge for the index episode.
5. Recurrence rate (ipsilateral or contralateral) measured by clinical or radiologic confirmation at 30-day and 12-month follow-up.
6. Need for definitive surgical intervention (e.g., VATS, pleurodesis, thoracotomy) recorded from CRF data within 12 months after index presentation.

7. Predictors of non-adherence and adverse outcomes (age, comorbidity, genetic syndromes, resource setting) analyzed using multivariable modeling from data collected at baseline and follow-up.
8. Functional recovery (return to school/work/sport) assessed at 12-month follow-up via patient record or reported data when available.

Completion date
03/11/2027

Eligibility

Key inclusion criteria
1. Patients of any sex aged under 18 years (pediatric) or 18 years and older (adult)
2. Presentation to a participating hospital with spontaneous pneumothorax (primary or secondary)
3. Index management episode (observation, aspiration, drainage, ambulatory device, or surgery) initiated at the participating site during the data collection window
4. Ability to follow up through medical records or clinical contact at 30 days and 12 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Traumatic pneumothorax resulting from blunt or penetrating chest injury.
2. Iatrogenic pneumothorax clearly related to medical or surgical procedures (e.g., central venous catheter insertion, thoracic surgery, pleural biopsy, barotrauma from mechanical ventilation), unless treated as spontaneous by the clinical team.
3. Perioperative or intraoperative pneumothorax occurring as an intended event during thoracic surgery.
4. Duplicate entries for the same clinical episode.
5. Patients for whom essential data on presentation or management cannot be obtained from medical records.

Date of first enrolment
04/05/2026

Date of final enrolment
02/11/2026

Locations

Countries of recruitment
United Kingdom

Austria

Czech Republic

France

Germany

Italy

Spain

Sweden

Türkiye

Study participating centre
Azienda Ospedaliera Universitaria Integrata (AOUI) Verona, Verona, Italy
p.le A. Stefani, 1
Verona
Italy
37126

Sponsor information

Organisation
Azienda Ospedaliera Universitaria Integrata Verona

ROR
https://ror.org/00sm8k518

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Azienda Ospedaliera Universitaria Integrata Verona

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon reasonable request from the GASP-OUT Steering Committee (contact: Principal Investigator – Federica Pederiva, email: federica.pederiva@aovr.veneto.it).
Details:
- Type of data shared: De-identified participant-level data (demographic, clinical, imaging, management, and outcome variables) collected via the standardized REDCap case report forms.
- Data availability: Data will become available 12 months after publication of the primary results and remain accessible for a minimum of 10 years.
- Access criteria: Requests must be submitted to the GASP-OUT Steering Committee and include a brief analysis proposal. Data will be shared under a non-negotiable data use agreement outlining conditions for secure storage, restricted use, and appropriate citation.
- Mechanism: Controlled access via secure institutional data-sharing platform hosted by the lead coordinating centre.
- Anonymisation: All data will be fully de-identified prior to sharing; no personal identifiers (e.g., name, exact date of birth, hospital ID) will be included.
- Ethical and legal considerations: Data sharing will comply with GDPR, HIPAA, and relevant national data protection laws.
- Consent: As an observational audit of standard care, consent requirements vary by jurisdiction; where required, participant or guardian consent/assent will be obtained and recorded.
- Purpose of sharing: To enable secondary analyses, systematic reviews, and international collaborations on pneumothorax management and outcomes.

IPD sharing plan summary

Available on request