

# An international prospective cohort study on spontaneous pneumothorax

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| <b>Submission date</b><br>22/10/2025   | <b>Recruitment status</b><br>Recruiting  | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>24/10/2025 | <b>Overall study status</b><br>Ongoing   | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>06/05/2026       | <b>Condition category</b><br>Respiratory | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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

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### Contact details

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## Additional identifiers

### 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**

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## **Ethics approval(s)**

approved 28/01/2026, TERRITORIAL ETHICS COMMITTEE AREA SOUTH WEST VENETO (c/o Azienda Ospedaliera Universitaria Integrata Verona P.le A. Stefani, 1, Verona, 37126, Italy; +39 45 8123236; comitatoetico@aovr.veneto.it), ref: 5495

## **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

**Total final enrolment**

0

**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

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

### Study outputs

| Output type                   | Details   | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> | version 1 | 06/10/2025   | 06/05/2026 | No             | No              |
| <a href="#">Study website</a> |           |              | 06/05/2026 | No             | No              |