Protocol ID: OSCILLONiCA-PL-Kids 01-2023
Version: 1.1
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Study Protocol

Official Title:Respiratory Oscillometry – Establishing Reference Values in Polish Children and Adolescents Aged 3–18 Years (OSCILLONiCA-PL-Kids)

Acronym: OSCILLONiCA-PL

NCT Number: NCTXXXXXXXX

Coordinating Center: Medical University of Gdańsk

Principal Investigator: Eliza Wasilewska, MD, PhD

Sponsor: Non-commercial investigator-initiated study

Synopsis

Primary Objective: Establish normative reference values for respiratory oscillometry (IOS) parameters (Rrs, Xrs, Fres, AX) in healthy Polish children and adolescents aged 3–18 years.

Secondary Objectives:
- Develop prediction equations.
- Create nomograms and percentile charts.
- Compare with international datasets.
- Evaluate feasibility of school-based oscillometry testing.

Study Design: Multicenter, observational, cross-sectional.
Population: Healthy Polish children and adolescents aged 3–18 years.
Sample Size: ~2,500.
Timeline: Start January 2023, data collection until June 2025, analysis and publications 2026.

1. Background and Rationale

Respiratory diseases are common causes of morbidity in children. Spirometry is the gold standard of lung function testing but requires patient cooperation, limiting its use in preschoolers. Impulse oscillometry (IOS) is non-invasive and feasible from age 3, requiring only tidal breathing. Despite its growing use, no Polish population-specific reference values exist. The European Respiratory Society (ERS) emphasizes the need for local reference equations. This study addresses this gap.

2. Objectives

Primary Objective: To establish reference values for IOS in healthy Polish children and adolescents aged 3–18 years.

Secondary Objectives include developing prediction equations, analyzing variability, comparing with other countries, creating nomograms, and establishing an open database.

3. Study Design

This is a multicenter, cross-sectional, observational study coordinated by the Polish Society of Pediatric Pulmonology across 12 centers in Poland. The study follows ERS technical standards and SPIRIT guidelines for observational protocols.

4. Study Population

Inclusion Criteria

Age 3–18 years.
Caucasian (born and residing in Poland).
Healthy children as defined by: no chronic lung disease; normal growth per WHO charts; no wheezing, cough, or dyspnea in the last 12 months; no acute respiratory infection within 4 weeks.
Written informed consent from parents/guardians; assent from adolescents ≥16 years.

Exclusion Criteria

History of asthma, cystic fibrosis, bronchopulmonary dysplasia, interstitial lung disease.
Acute respiratory infection within 4 weeks prior to testing.
Severe comorbidities (congenital heart disease, neuromuscular disorders).
Chest wall deformities.
Inability to perform IOS according to ERS standards.

5. Recruitment and Sampling

Participants are recruited through schools, kindergartens, and pediatric outpatient clinics in 12 centers across Poland. Recruitment includes distribution of information sheets, informed

consent forms, and health questionnaires to parents. Non-probability (convenience) sampling is applied, ensuring representation across age, sex, and geographic regions.

6. Study Procedures

Training of Operators

All staff complete centralized training including physiology of oscillometry, interpretation of artifacts, and hands-on demonstrations. Certification is required before participation; refresher training and audits are conducted periodically.

Environment and Setup

Measurements are conducted in quiet school rooms, typically the nurse's office. Equipment includes oscillometer (Jaeger), stadiometer, and weighing scale. Calibration is performed daily per manufacturer's recommendations.

Anthropometry

Height measured barefoot using stadiometer, weight measured in light clothing. Data recorded into study database. BMI calculated for descriptive analyses.

Oscillometry Testing

Participants seated, back supported, head neutral, nose clip applied. Cheeks supported by examiner. Children breathe quietly through a mouthpiece for 30–45 seconds. At least 3 technically acceptable recordings obtained. Median values analyzed. Criteria: no coughing, talking, leaks; repeatability ≤15% CoV. Parameters recorded: Rrs5, Rrs10, Rrs20, Xrs5, Xrs10, Xrs20, Fres, AX.

7. Equipment and Standardization

All centers use identical Jaeger oscillometers with standardized SOPs. Disposable mouthpieces provided. Centralized training, SOP manuals, and regular audits ensure consistency.

8. Statistical Analysis Plan

Sample size: ~2,500 participants. Data integrity checked automatically. Reference equations developed using Generalized Additive Models for Location, Scale and Shape (GAMLSS), LMS method. Model selection guided by Schwarz Bayesian Criterion. Comparisons with international cohorts performed. Sensitivity analyses exclude borderline cases (e.g., parental smoking exposure).

9. Ethics and Regulatory Aspects

Approved by the Bioethics Committee of the Medical University of Gdansk (No. 106/2023). Complies with Declaration of Helsinki. Informed consent from

parents/guardians; assent from children ≥16 years. Confidentiality and GDPR compliance ensured.

10. Data Management and Quality Assurance

Data entered into encrypted system; identifiers separated from clinical data. Local coordinators oversee SOP adherence. Central monitoring and audits applied. Paper consent forms stored securely for 10 years.

11. Dissemination and Impact

Findings disseminated via peer-reviewed journals, conferences, and guidelines of the Polish Society of Pediatric Pulmonology. De-identified datasets available upon request. Results expected to support clinical practice and GLI initiatives.

12. Patient and Public Involvement

Parents and schools engaged through meetings and written materials. Health questionnaire pilot-tested for clarity. Lay summaries of results will be distributed to schools and families.

13. Study Status and Timeline

Start: January 2023. Data collection until June 2025. Analysis: 2025–2026. Results publication planned for 2026.

14. Strengths and Limitations

Strengths: large multicenter sample, standardized devices and SOPs, wide age coverage, alignment with ERS standards.
Limitations: underrepresentation of rural schools, smaller subsamples at youngest and oldest ages, residual variability.

15. Funding, Conflicts of Interest, Acknowledgements

Funding: Medical University of Gdańsk. No conflicts of interest declared.
Acknowledgements: Polish Society of Pediatric Pulmonology, participating schools, parents, and children.

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Inform Consent Form

Study: Oscillometry reference values for Polish children and adolescents

Official Title: Respiratory Oscillometry – Establishing Reference Values in Polish Children and Adolescents Aged 3–18 Years (OSCILLONiCA-PL Kids)

Acronym: OSCILLONiCA-PL Kids

Dear Parent/Guardian,

Your child is invited to participate in a multicenter scientific study aimed at establishing reference values for oscillometry (impulse oscillometry, IOS) in healthy Polish children and adolescents. The study is coordinated by the Polish Society of Paediatric Pulmonology.

Purpose of the study

The purpose of this study is to determine normal ranges of oscillometric parameters of lung function in children and adolescents aged 3–18 years. These results will help physicians in Poland and worldwide to better diagnose and monitor respiratory diseases in children.

Study procedures

- The examination will take place in your child's school or kindergarten, in a designated room.
- Your child's height and weight will be measured.
- A short health questionnaire will be completed based on your information.
- Your child will undergo oscillometric lung function testing using a non-invasive, standardized device. The test involves quiet breathing into a mouthpiece for a short period (approx. 30–60 seconds).

Risks and safety

The examination is safe, painless, and non-invasive. The only possible inconvenience may be mild fatigue or lack of cooperation during the test.

Data protection

All collected data will be anonymized and processed in accordance with the European Union General Data Protection Regulation (GDPR). Results will be used exclusively for scientific purposes.

Voluntary participation

Participation in this study is entirely voluntary. You may refuse or withdraw your consent at any time without giving a reason and without any consequences for your child.

Statement of consent

I hereby declare that I have read the above information and had the opportunity to ask questions. I understand the purpose and procedures of the study, and I voluntarily consent for my child to participate.

Child's details
- Full name: .....
- Date of birth: .....

-Signature: ..... Date: .....

Parent/Guardian details
- Full name: .....
- Signature: ..... Date: .....