FOCUS

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Ethical review	Positive opinion
Status	Pending
Health condition type	Infections - pathogen unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON57495

Source
Onderzoeksportaal

Brief title
FOCUS

Condition

- Infections - pathogen unspecified

Synonym
Respiratory infections

Research involving
Human, Data

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

- Other intervention

Explanation

N.a.

Outcome measures

Primary outcome

This is a descriptive study, the primary outcomes include the frequency of resource utilization in terms of the performance of diagnostic tests (e.g. RVTs, laboratory test and chest X-rays performed yes/no) and applied therapeutic interventions (nebulization and type of antibiotic prescription).

Secondary outcome

As secondary outcome patterns in reasoning and decision-making processes regarding resource utilization will be analyzed.

Study description

Background summary

Ensuring that children who present to the Emergency Department (ED) receive appropriate care is of great importance. On the other hand, it is critical to avoid excessive care, particularly in the form of unnecessary diagnostic and therapeutic procedures. Such procedures can be traumatic for, especially pediatric, patients and may contribute to rising healthcare costs and increased ED crowding. Next to that, excessive testing may lead to clinically irrelevant findings and induce additional testing and interventions. Despite this, there is limited knowledge regarding the extent and reasoning behind the performance of unnecessary resource use for pediatric patients in the ED setting.

Study objective

The primary objective of this research is to assess the occurrence, variability and underlying causes of treating pediatric patients with respiratory infections at the ED. This is done in order to identify and ultimately de-implement ineffective practices.

Study design

We will perform a 2 week nationwide observational cross-sectional study using a flash mob design.

Intervention

N.v.t.

Study burden and risks

There is no additional burden or risk to the patient as data collection will include only data collected within routine clinical practice; no additional information will be asked of patients. Also, all data will be anonymized so that individual personal data will not be traceable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Newborns
Babies and toddlers (28 days-23 months)
Children (2-11 years)

Inclusion criteria

Consecutive sampling will be used to recruit a broad range of participants which would represent the population of children who present to the ED with respiratory infections. In order to be eligible to participate in this study, a subject must meet all of the following criteria:

All patients <18 years of age with fever or a history of fever and respiratory complaints (coughing, difficulty breathing, wheezing, SpO2 <94%, chest wall retractions, tachypnea, runny nose, sore throat, or some other suspicion of respiratory infection) visiting a participating pediatric ED during a continuous two-week period in January 2026.

Also, all physicians treating the included children will be invited to participate. This includes physicians who, possibly under supervision, make key decisions regarding the provided care to these patients. Their inclusion is essential to assess factors influencing clinical decision-making.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: patients immediately transferred to the pediatric intensive care or patients requiring immediate lifesaving interventions.

For treating physicians there are no exclusion criteria.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2026
Enrollment:	300
Duration:	1 months (per patient)
Type:	Anticipated

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Not available

Date:	28-03-2025
Application type:	First submission
Review commission:	CCMO

Positive opinion

Date:	24-03-2025
Application type:	First submission
Review commission:	Niet WMO Toetsingscommissie Erasmus MC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Research portal	NL-009504