Risk factors for Intensive Care admission of children with severe acute wheeze or asthma

Published: 18-04-2016
Last updated: 16-04-2024

Primary Objective: To prospectively assess the impact and relevance of several risk factors for SAA/acute wheeze that have been identified in retrospective studies, including our own. Secondary Objective: To assess short-term medical and…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON44930

Source
ToetsingOnline

Brief title
Status Asthmaticus on the Intensive Care Prospective - STATIC PRO

Condition

- Bronchial disorders (excl neoplasms)

Synonym
life-threatening asthma attack, Status Asthmaticus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ammodo;Stichting Astma Bestrijding;Crowd funding SKIC

Intervention

Keyword: Asthma, Children, PICU, Risk Factors

Outcome measures

Primary outcome

Undertreatment, defined as:

Patient is not using inhaled corticosteroids (ICS), or

Patient is using ICS for <7 days (counting from moment of admission to emergency department) according to treatment plan, or

Patient is not using ICS according to treatment plan.

Use of medication is estimated through obtaining pharmacy records on medication that was picked up by the patient, versus the medication that is required according to the treatment plan. If a patient indicates that he/she did not use their medication correctly (despite pharmacy records indicating pickup), this patient is counted as being "undertreated".

Secondary outcome

* Exposure to air pollution/airborne particulate matter (PM10), acute (<48h).

* Exposure to furry animals in the primary home (as reported by parents) to which the child is sensitised.

* Exposure to house dust mite in the primary home, if the child is sensitised (>0,1kU/L on RAST).

* Exposure to cigarette smoke, as measured by cotinine in urine.

* Type of virus in upper airway tract.

* Socio-economic status, defined by highest education of both parents and

occupation of both parents.

* Severity of asthma at follow-up, defined as *3 on GINA treatment level.

* A previous admission to a hospital (MC) for asthma.

* A previous admission to a PICU for asthma.

* Distribution of ADRB2-receptor polymorphisms, compared to the non-SAA population.

* CBCL scores. The CBCL uses a continuous scale (interval) where a higher score indicates more problems within a certain area of interest.

* PA(C)QLQ scores. The PAQLQ and PACQLQ use continuous scales (interval) where a higher score indicates better quality of life.

* SVLK-k/o. The SVLK-k and *o use continuous scales (interval) where a higher score indicates more severe PTSD.

Study description

Background summary

Most asthma guidelines offer evidence-based or best practice approaches to the management of asthma exacerbations but struggle with the presentation of a robust evidence-based approach for severe acute asthma exacerbations (SAA) or acute wheeze. Retrospective research indicates that preventive measures could be installed when the pathophysiology or *clinical phenotype* of children with SAA/acute wheeze is better understood. In addition, this could enable more effective treatment, leading to quicker resolution of exacerbations, with less functional morbidity. In our retrospective multicentre case control study, 4 risk factors remained significant: active or passive smoking, allergies, earlier hospitalisation for asthma, and non-sanitised homes. Other studies suggest that undertreatment of asthma or specific viruses like Rhinovirus Type C are relevant risk factors.

Study objective

Primary Objective: To prospectively assess the impact and relevance of several

risk factors for SAA/acute wheeze that have been identified in retrospective studies, including our own.
Secondary Objective: To assess short-term medical and psychosocial functioning in patients (and parents) admitted to a PICU for SAA/acute wheeze versus a control group admitted to an MC for SAA/acute wheeze.

Study design

Observational, prospective comparative cohort study

Study burden and risks

The risk associated with participation is negligible, the burden minimal. Each patient and/or his parent(s)/legal guardian will be asked to fill out several questionnaires, regarding the disease, treatment, psychosocial functioning etc. These questionnaires contain no items of a sensitive nature. Collection of blood for Radio Allergo-Sorbent Test (RAST) is part of standard care in patients with SAA. Collection of a nasal swab to determine viral infection is not part of standard care, but poses minimal additional burden to the patient. Collection of a urine sample for cotinine is not part of standard care, but poses no additional burden to the patient. Collection of an additional 0.5ml of blood to determine ADRB2-receptor polymorphisms is not part of standard care, but poses no additional burden to the patient. All hospital visits fall within standard care, namely the initial hospital admittance and stay, and subsequent outpatient follow-up by a paediatrician/paediatric pulmonologist (including a lung function test in patients older than 4 years of age).
This study can only be performed in children, as paediatric asthma and SAA differ greatly from the same disease in adults.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

-Between 2 and 18 years of age
-Admission to a PICU for status asthmaticus or acute wheeze
-Admission to a MC for status asthmaticus or acute wheeze

Exclusion criteria

-Patient is outside of specified age range
-Patient has Down*s Syndrome
-Patient has a congenital/acquired heart defect that interferes with normal SAA treatment
-Patient has a congenital/acquired airway defect (Tracheomalacia, Bronchomalacia)
-Patient has a primary/secondary immunodeficiency
-Patient has a pre-existing chronic pulmonary condition, known to mimic asthma: Cystic fibrosis, Bronchopulmonary dysplasia, Bronchiolitis obliterans.
-Any subject who receives a different diagnosis than SAA / asthma exacerbation within the timeframe of the admission
-Any subject who does not provide informed consent or repeals informed consent (either by patient or by guardian(s)).

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2016
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-10-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL52508.078.15