Evaluation of different treatment thresholds in a clinical pathway for children with acute asthma

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Evaluation of the effect of different treatment thresholds in a clinical pathway for children with acute asthma who are treated with supplemental oxygen

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON50952

Source
ToetsingOnline

Brief title
Clinical pathway for acute asthma in children

Condition

- Bronchial disorders (excl neoplasms)

Synonym
acute asthma, asthma exacerbation

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Er wordt sponsoring aangevraagd bij het Martini wetenschapsfonds voor de Castor database

Intervention

Keyword: acute asthma, asthma score, child, clinical pathway

Outcome measures

Primary outcome

Primary outcome is the difference in admission time for children with acute asthma who are treated according to the current nurse-driven pathway or the new pathway with adjusted treatment thresholds for patients who need supplemental oxygen.

Secondary outcome

Secondary outcomes are

-number of bronchodilator adminstrations per patient,

-the number of deviations from the pathway; administration of bronchodilators when not indicated or when bronchodilators were indicated but not administered.

-number or assessments by attending physician

-number of patients excluded because they needed treatment with intravenous albuterol

-number of re-admission within one week

-association between heart rate and the total CAS en individual items of CAS

-difference between groups in administration of intravenous magensiumsulphate

-difference between groups in transfer to pediatric intensive care unit

Study description

Background summary

The administration of bronchodilators for acute asthma is based on serial assessments of the patient*s respiratory status. In daily practice, this may result in variability and/or delay in the decision-making process to wean or intensify bronchodilator administration. We aim to improve the quality of care by standardizing inpatient asthma care and reduce the length of stay. Clinical pathways for acute asthma outline a sequence for assessment and interventions. They have reduced admission time and healthcare costs. Several asthma scores have proven to be useful in clinical pathways. However, all asthma scores require auscultation of the lungs to score the degree of wheezing or air entry. Therefore, all healthcare providers should be sufficiently trained in auscultation of the lungs before the possible implementation of such a score. This prompted us to develop an asthma score that does not require auscultation of the lungs. This innovative asthma score was adapted from the physical findings in pediatric asthma scores validated previously. We recently demonstrated that this childhood asthma score (CAS) could accurately predict the bronchodilator nebulization requirement compared to the routine clinical judgment of the attending physician to administer bronchodilators. Subsequently, we conducted a study to implement a nurse-driven clinical pathway based on our innovative asthma score.

This pathway included standardized respiratory assessments and a protocol for the nursing staff to administer bronchodilators without a specific order from the physician. We compared the length of stay and the number of readmissions to a historical cohort. Patients treated according to the nurse-driven protocol were 3.3 times more likely to be discharged earlier (hazard ratio, 3.29; 95% confidence interval, 2.33-4.66; $P < 0.05$), and length of stay was significantly reduced (median 28 versus 53 h) compared to the historical standard practice. Patient safety was not compromised, and none of the patients were removed from the pathway.
Although the nurse-driven clinical pathway decreased length of stay without compromising patient safety, one major drawback was frequently reported. Patients who need supplemental oxygen had a CAS score of at least 4, indicating the need for bronchodilator therapy, even though it appeared that the patient was not tachypnic nor dyspneic (eg, when the patient was asleep). This can be explained by the fact that low oxygen saturation may result from atelectasis and ventilation/ perfusion mismatch without small airway obstruction.
The results of our previous study encourage us to further evaluate and adapt the pathway for patients who need supplemental oxygen. In this randomised study, length of stay and safety for patients who need supplemental oxygen treated according to the current pathway will be compared to a pathway with adjusted treatment thresholds.

Study objective

Evaluation of the effect of different treatment thresholds in a clinical pathway for children with acute asthma who are treated with supplemental oxygen

Study design

A randomized non-inferiority study. We aim to demonstrate that adjustment of the treatment threshold for children who are treated with supplemental oxygen does not result in a longer length of stay. We consider a difference of 8 hours as clinically relevant.

Intervention

The intervention comprises adjusted treatment thresholds for patients with acute asthma who need supplemental oxygen.
If randomised to the standard care nurse-driven pathway the treatment thresholds will be according to current cut-off values, CAS <4, CAS 4-6, CAS 7-8 and CAS 9-12. Figure 2 page 17 protocol.

If the patient is randomised to the new pathway, patients treated with supplemental oxygen will be treated with bronchodilators based on adjusted CAS scores. The cut off values for the first two treatment thresholds will be CAS <5, CAS 5-6, respectively.
Treatment thresholds will not change for moderate or severe acute asthma (CAS 7-8 en CAS 9-12).
Figure 3 page 18 protocol.

Study burden and risks

Acute asthma is one of the most common reasons for hospital admission in childhood.
We have demonstrated that a nurse-driven clincial pathway significantly reduces admisson time without compromising patient safety.
The results of our previous study encourage us to further evaluate and adapt the pathway for patients who need supplemental oxygen.
Patients are treated with bronchodilators, and as needed systemic corticosteroids, supplemental oxygen and intravenous magnesiumsulphate.according to the current Dutch guideline for acute asthma.
For patients who need supplemental oxygen, only the treatment thresholds for mild acute asthma will be adjusted.
Furthermore
-In case of severe asthma (score >8) the attending physician is called to assess the patient's respiratory status
-The nurse can call the attending physician to assess the patient at their own discretion
-Patients heartrate, respiratory rate and transcutaneous oxygen saturation are continously monitored.

-Pediatric early warning scores are used in our department to detect deterioration of the patient

With these precautions we expect minimal risk for the patients.

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

-children 2-18 years of age admitted for acute asthma
-treatment for acute asthma according to current dutch guideline
-supplemental oxygen use, low flow or high flow

Exclusion criteria

-severe acute asthma for which intravenous albuterol is indicated
-unstable heart disease
-cystic fbrosis or other chronich or congenital lung disease
-any neurological disease
-any muscular disease
-developmental delay

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2022
Enrollment:	130
Type:	Actual

Medical products/devices used

Generic name:	Childhood Asthma Score algorithm software
Registration:	No

Ethics review

Approved WMO

Date:	23-08-2021

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-08-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-08-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	04-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL76447.042.21