Identifying the critically ill paediatric oncology patient

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24811

Source
Nationaal Trial Register

Brief title
SO-PEWS

Health condition

paediatric cancer

Sponsors and support

Primary sponsor: KiKa grant number 287
Source(s) of monetary or material Support: KiKa

Intervention

Outcome measures

Primary outcome

The primary outcome will be the combined end point of a non-elective PICU admission or cardiopulmonary resuscitation.

Secondary outcome

The secondary outcomes of the study are hospital and PICU mortality; significant clinical deterioration event (a composite adverse outcome of the comprised treatment(s) provided in the 12 hours prior to transfer to PICU from an inpatient ward); hospital and PICU length of stay; rapid response team calls and urgent PICU consultations, and adherence to the BedsidePEWS scoring algorithm.

Study description

Background summary

Hospitalised paediatric oncology patients are at risk to develop acute complications. Early identification of clinical deterioration enabling adequate escalation of care remains challenging. Various Paediatric Early Warning Scores (PEWSs) have been evaluated, also in paediatric oncology patients but mostly in retrospective or case control study designs. This study encompasses the first prospective cohort to evaluate the predictive performance of the Bedside Paediatric Early Warning Score (BedsidePEWS) in hospitalised paediatric oncology patients for non-elective PICU admission or cardiopulmonary resuscitation. If the predictive value proves to be suboptimal, simultaneous collection of routine health care and patient monitor data enables us to fit a model for this particular high-risk population. Our ultimate goal is to provide a valuable prediction tool that timely detects critical deterioration in paediatric cancer patients, allowing for adequate (timing of) clinical intervention. This prospective cohort study is conducted at the Princess Máxima Centre, an 80-bed Dutch paediatric oncology hospital, directly connected to a shared 22-bed paediatric intensive care unit (PICU).

Study objective

We hypothesize that the BedsidePEWS might not have optimal predictive performance for clinical deterioration resulting in unplanned PICU transfer or cardiopulmonary resuscitation in hospitalised paediatric oncology patients and might need optimisation.

Study design

Prospective observational cohort study between Feb 1st 2019 and Sep 1st 2021 - continuous data collection.

Contacts

Public
Princess Máxima Centre for Paediatric Oncology
Marijn Soeteman

06-22484486
Scientific
Princess Máxima Centre for Paediatric Oncology
Marijn Soeteman

06-22484486

Eligibility criteria

Inclusion criteria

All patients with ICD-O diagnosis of paediatric malignancy, aged 0 - 18 years, admitted to one of the inpatient wards of the Princess Máxima Centre.

Exclusion criteria

Patients admitted as outpatients for routine diagnostic and therapeutic procedures will be excluded. Patients with restrictions in care (palliative care only, do not resuscitate orders, no PICU admission) will be excluded from the moment restriction in care is registered.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2019
Enrollment:	1500

Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	06-10-2020
Application type:	First submission

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
NTR-new	NL8957
Other	METC Utrecht : METC 16-572/C

Study results