The association between vital signs, biochemical signs of acute organ failure, and relevant clinical outcomes in emergency department patients of different age categories

No registrations found.

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

Summary

ID

NL-OMON22957

Source
NTR

Brief title
AGED

Health condition

All ED patients containing and Trauma, sepsis, etc.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: SGO fund

Intervention

Outcome measures

Primary outcome

Mortality

Secondary outcome

ICU admission

Study description

Background summary

Rational:
Appropriate interpretation of vital signs and biochemical signs of organ failure (assessed with blood testing) are important for recognition of early deterioration and risk stratification of emergency department (ED) patients. Risk stratification is used to decide what initial ED treatment is administered and what definitive level of care is needed (i.e. ward, medium care or intensive care unit (MCU/ICU)), affecting patient outcomes. Previous studies suggest that screening and risk stratification tools are inappropriate for older ED patients because of poor interpretation of vital signs and biochemical signs of acute organ failure, which may be caused by non-existing or inappropriate cut-off values. We hypothesize that this is caused by changing reference values for vital signs and biochemical signs of acute (i.e. hyperlactatemia) organ failure in adult ED patients with increasing age, correspondent to the paediatric patient population. To prove that cut-offs for vital signs and biochemical signs of organ failure do not exist or change with increasing age, large datasets are needed.

Objectives:
Objective 1: To assess the frequency of hospital admission, hospital length of stay (LOS), in-hospital mortality and 7-day revisits in ED patients in different age categories in whom vital signs are (not) registered.
Objective 2: To assess the association between vital signs, biochemical signs of acute organ failure and (case-mix adjusted) relevant clinical outcomes in different age categories.
Objective: 3: To assess if the presenting complaint and diagnosis (i.e. sepsis or trauma) affects the association between vital signs, biochemical signs of acute organ failure and relevant clinical outcomes in different age categories.

Study design: Retrospective multi-centre cohort study using the Netherlands Emergency department Evaluation Database (NEED).

Main study parameters/endpoints:
Hospital admission (to ward or MCU/ICU), in-hospital mortality, hospital LOS, 7-day ED revisit.

Benefits: The present study will contribute to improved recognition and age-adjusted risk stratification of ED patients. It has the potential to improve numerous guidelines used for risk stratification of ED patients as the currently used cut-off points in risk stratification tools may need adjustment. Finally it may lead to adjusted endpoints for resuscitation in the ED.

However, for the ED patients already included in the database the present study will have no benefit unless they revisit our ED in the future.
Burden: Not applicable.
Risks: Not applicable.

Study objective

Cut-off values for vital signs and blood values don't exist, or change with age

Study design

Discharge out of hospital or mortality in-hospital, Direct ICU admission from Emergency derpartment

Contacts

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Eligibility criteria

Inclusion criteria

All consecutive ED patients >17years

Exclusion criteria

No vital signs measured or no blood tests performed

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:	Recruitment stopped
Start date (anticipated):	01-01-2020
Enrollment:	170000
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-03-2020
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	NL8422
Other	Commissie Medische Ethiek van het LiJMC : G19.030

Study results