Machine Learning for Risk Stratification in the Emergency Department: A Pilot Clinical Trial

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To determine the feasibility of a full-scale randomised controlled trial evaluating the clinical effectiveness of the RISKINDEX based on experience gained from conducting this pilot RCT. ML mortality predictions will be compared with clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54014

Source
ToetsingOnline

Brief title
MARS-ED

Condition

- Other condition

Synonym
n.v.t.

Health condition

Acute aandoeningen bij patiënten op de SEH

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: emergency department, machine learning, mortality prediction, risk stratification

Outcome measures

Primary outcome

- Calculated ML risk scores and observed mortality, to evaluate discriminatory performance of ML risk score to predict 31-day mortality.

- Physicians self-reported policy changes to evaluate whether presentation of the ML risk score causes changes in clinical decision making. Policy changes include treatment policy, requesting ancillary investigations, treatment restrictions (i.e., no intubation or resuscitation).

Secondary outcome

- Clinical endpoints such as 31-day mortality, ICU and MC admission and readmission will be compared between the control an intervention group to evaluate differences.

- Diagnostic performance of other clinical risk scores and physicians will be compared to the ML score.

Study description

Background summary

Identifying emergency department (ED) patients at high and low risk shortly after admission could help decision-making regarding patient care. Several clinical risk scores and triage systems for stratification of patients have

been developed, but often underperform in clinical practice. Moreover, most of these risk scores only have been diagnostically validated in an observational cohort, but never have been evaluated for their actual clinical impact. In a recent retrospective study that was conducted in the Maastricht University Medical Center (MUMC+), a novel machine learning (ML) model was introduced that predicted 31-day mortality of sepsis patients presenting to an ED. Follow-up studies underlined the potential of the model also in a prospective set-up. However, it remains unknown to what extent these models have any beneficial value when it is actually implemented in clinical practice.

Study objective

To determine the feasibility of a full-scale randomised controlled trial evaluating the clinical effectiveness of the RISKINDEX based on experience gained from conducting this pilot RCT. ML mortality predictions will be compared with clinical impression of physicians. Furthermore, the impact of the ML model on clinical decision making will be monitored.

Study design

The MARS-ED study is designed as a multi-center, randomized, open-label, non-inferiority pilot clinical trial.

Intervention

Physicians will be presented with the ML risk score of the patients they are actively treating, directly after assessment of regular diagnostics has taken place.

Study burden and risks

The only intervention in this study is presentation of a ML risk score to the treating physician. However, this risk estimation might influence clinical decision making and may result in ordering ancillary testing or extra consultations. These extra investigations will probably not harm the patient and may even improve diagnostics. In addition, the higher mortality prediction made by the ML model will stimulate the physician to check once more on his/her judgment of the patient and will probably help to improve this judgement. We conclude that the benefits outweigh the risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adult, defined as >= 18 years of age
- Assessed and treated by an internal medicine specialist in the ED
- Willing to give written consent, either directly or after deferred consent procedure

Exclusion criteria

- <4 different laboratory results available (hematology or clinical chemistry) within the first two hours of the ED visit (calculation ML prediction score otherwise not possible)
- Unwilling to provide written consent, either directly or after deferred consent procedure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-09-2022
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	20-06-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	n.n.t.b.
CCMO	NL78478.068.21