External validation of the beta-lactam target non-attainment (BATMAN) risk score in adult ICU patients: a diagnostic multivariate predictive risk model

Published: 20-03-2023
Last updated: 13-05-2024

The primary objective is an external validation of the beta-lactam target non-attainment (BATMAN) risk score, a four-routinely available prediction model in adult critically ill patients with a convenient scoring system in Dutch hospitals.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56247

Source
ToetsingOnline

Brief title
BATMAN

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
critically ill patients, Infection

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Beta-Lactams, ICU, Pharmacodynamics, Pharmacokinetics

Outcome measures

Primary outcome

The individual BATMAN risk score values are calculated for each patient. The calibration of the risk score will be assessed with a calibration plot, where the predicted outcome (x-axis) will be plotted against the observed outcome (y-axis). The discrimination of the diagnostic risk score will be displayed in the concordance index, which is identical to the area under the receiver operating curve.

Secondary outcome

The secondary parameters are the classification measures such as the positive predictive value, negative predictive value, misclassification, sensitivity and specificity.

The positive predictive value describes the ability of the risk score to identify subjects that will not achieve target attainment. The negative predictive value describes the ability of the risk score to identify subjects that will achieve target attainment. The sensitivity describes the correctly identified subjects that will not achieve target attainment, the specificity describes the correctly identified subjects that will achieve target attainment and the misclassification describes the total number of incorrectly identified

patients that will or will not achieve target attainment.

Study description

Background summary

Intensive care unit (ICU) patients are a highly heterogenic group of patients that undergo extensive physiological alterations that will have impact on antibiotic pharmacokinetics, such as beta-lactam antibiotics. For the beta-lactams, achievement of an adequate drug level is associated with a higher likelihood of clinical success and a decrease in the potential for antimicrobial resistance. In order to predict which ICU patients would benefit from therapeutic drug monitoring of beta-lactam antibiotics, a diagnostic multi-variable prediction model was developed using the data from the EXPAT and DOLPHIN studies. Variables in the diagnostic multi-variable prediction model were then used to develop a risk score. This risk score intents targeted use of beta-lactam antibiotic therapeutic drug monitoring in patients who are expected to not achieve target exposure.

Study objective

The primary objective is an external validation of the beta-lactam target non-attainment (BATMAN) risk score, a four-routinely available prediction model in adult critically ill patients with a convenient scoring system in Dutch hospitals.

Study design

A prospective multicenter cohort study.

Study burden and risks

With the exception of blood sampling, there is no intervention in this study that may affect patient treatment. Antibiotic dosing will occur as deemed by the treating clinician and their local dosing practices.

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

All patients admitted to the adult general ICU wards and given standard of care intravenous therapy of the target antibiotic are screened for eligibility. In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Written informed consent has been obtained from the patient or their legally authorised representative
• Age >=18 years
• Treated with one of the following beta-lactam antibiotics at the ICU with intermitted dosage.
o Amoxicillin
o Amoxicillin with clavulanic acid
o Cefotaxime
o Ceftazidime
o Cefuroxime
o Flucloxacillin
o Meropenem
o Piperacillin with tazobactam
• Eligible blood material within 36 hours after start of beta-lactam antibiotic

to determine target attainment (100%*T > MICECOFF).
• Suitable intravenous/intra-arterial access to facilitate sample collection

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Written consent has not been obtained
• <18 years
• Pregnancy
• Beta-lactam antibiotic cessation before blood sample collection
• Receiving beta-lactam antibiotic only as prophylaxis
• No intravenous/intra-arterial access
• Patients with renal replacement therapy
• Patients with burn injury

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2023
Enrollment:	148
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-03-2023
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-12-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-05-2024
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
ClinicalTrials.gov	NCT05542771
CCMO	NL81245.078.22