Changes in predictive capacity when adding Ticagrelor and Clopidogrel to an existing allogeneic bloodtransfuion prediction model for cardiac surgery.

No registrations found.

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

Summary

ID

NL-OMON22097

Source
NTR

Brief title
RUBY

Health condition

Coronary heart disease, valvular disease, vascular disease

Sponsors and support

Primary sponsor: Department of Cardiac Surgery and Department of Anesthesia Amsterdam UMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

How accurately does the TRACK model predict allogeneic blood transfusions in the Amsterdam UMC, location AMC, cardiothoracic surgery population?

Secondary outcome

1. How does the predictive capacity of the TRACK model change when the pre-operative use of P2Y12 inhibitors are added as a predictive factor?
2. What is the relationship between pre-operative P2Y12 use and amount and type of blood product transfused
3. Is there a difference in the use of transfusion products between Ticagrelor and other P2Y12 inhibitors, such as Clopidogrel?
4. Is there a difference in length of hospital stay, and the 30/90 day mortality in patients using Ticagrelor, when compared to other P2Y12 inhibitors such as Clopidogrel?

Study description

Background summary

The Transfusion Risk and Clinical Knowledge (TRACK) model was developed in 2008 in an Italian adult cardiac surgery population and consists of the following 5 predictive factors: sex, age, weight, pre-operative haematocrit and complexity of surgery(6). The decision to use this specific model was based on its simplicity and relatively high predictive capacity, in comparison to other models with higher numbers of complex factors. This model has an allogeneic blood transfusion predictive capacity of 72% and uses a point system to divide patients into different risk groups, according to the total number of points allocated. During the derivation of this model in 2008, dual anti-platelet medication was included, but no significant association was found. In the 12 years since development, the popularity of dual anti-platelet medication used in acute coronary syndrome patients, has significantly improved and its association with post-operative bleeding and allogeneic blood transfusion has been suggested(10, 11).

Validating this model might aid clinicians in reducing allogeneic blood transfusions, transfusion complications and associated costs. Ultimately this might aid development of patient specific transfusion strategies and new blood management protocols.

The aim of this study is to externally validate the TRACK blood transfusion prediction model in our population. Additionally, we will study the impact of adding the preoperative use of dual antiplatelet medication, as extra predictive factor, to the TRACK blood transfusion prediction model and determine the effect on predictive capacity.

Study objective

The aim of this study is to externally validate the TRACK blood transfusion prediction model in our population. Additionally, we will study the impact of adding the preoperative use of

dual antiplatelet medication, as extra predictive factor, to the TRACK blood transfusion prediction model and determine the effect on predictive capacity.

Study design

Pre operative: Baseline Characteristic, Vital Signs, Laboratory values, transfusions,
Intraoperative: Extracorporeal Characteristics, Vital Signs, Laboratory values, transfusions
Post operative: Vital Signs, Laboratory values, transfusions, 30 day mortality, 90 day mortality

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

• Patients > 18 years
• Patients receiving on-pump cardiac surgery.
• Patients receiving off-pump cardiac surgery.

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in the data collection:

• Cardiac surgery for congenital disorders

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):	12-05-2021
Enrollment:	3500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-05-2021
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	NL9464
Other	METC Location AMC : W21_265 # 21.291

Study results