Transfusion strategies in women during Major Obstetric Haemorrhage

No registrations found.

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

Summary

ID

NL-OMON28409

Source
Nationaal Trial Register

Brief title
TeMpOH-1

Health condition

Major Obstetric Haemorrhage

Sponsors and support

Primary sponsor: Center for Clinical Transfusion Research (Sanquin Leiden) and Leiden University Medical Center
Source(s) of monetary or material Support: Sanquin Blood Supply Foundation

Intervention

Outcome measures

Primary outcome

Maternal mortality and severe maternal morbidity. Severe maternal morbidity will be defined as a postpartum hysterectomy, postpartum arterial embolisation and/or intensive care unit admission.

Secondary outcome

N/A

Study description

Background summary

Major obstetric haemorrhage is the most important cause of severe maternal morbidity. Observational studies on massive haemorrhage associated with trauma and surgery have shown an apparent survival advantage with the administration of high cumulative ratios plasma and platelets to red blood cells. However, these results may have been confounded due to reverse causation and do not take time-varying treatment and time-dependent confounding into account. Furthermore, some authors recently proposed that not the ratios between the transfused blood components determine the outcome, but rather the timing of transfusion of plasma and platelets. Administration of plasma and platelets early on in treatment would prevent and timely correct coagulopathy during ongoing blood loss, and would thus lead to more favourable outcomes.
The aim of this study is to determine the effect of early administration of plasma and platelets alongside RBCs on the clinical course of women with obstetric haemorrhage compared to administration at a later stage in treatment.
Women that received FFP and/or platelets alongside RBCs due to obstetric haemorrhage, in 2011 and 2012 in the Netherlands, will be identified by cross-referencing data from departments of blood transfusion services with data from local birth registers. Data on characteristics of and treatment of selected women will be collected by performing a chart review of patients. The effect of timing of transfusion of FFP and/or platelets in conjunction with RBC transfusion on maternal mortality and severe maternal morbidity will be determined by using an inverse probability weighted Cox proportional hazard model.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Transfusion of FFP and/or platelets alongside RBC transfusion
AND
Obstetric haemorrhage in pregnancy (including early pregnancy), during the first 24 hours following delivery or in puerperium (limited to 6 weeks after delivery).

Exclusion criteria

Timing of transfusion of blood components not recorded or not obtainable.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2013
Enrollment:	1600
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-07-2013
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	NL3909
NTR-old	NTR4079
Other	MEC Leiden University Medical Center : P12.273
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A