Transfusion strategies in women during Major Obstetric Haemorrhage

Gepubliceerd: 17-07-2013 Laatst bijgewerkt: 18-08-2022

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28409

Bron
Nationaal Trial Register

Verkorte titel
TeMpOH-1

Aandoening

Major Obstetric Haemorrhage

Ondersteuning

Primaire sponsor: Center for Clinical Transfusion Research (Sanquin Leiden) and Leiden University Medical Center
Overige ondersteuning: Sanquin Blood Supply Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Center for Clinical Transfusion Research (Sanquin Research)
Plesmanlaan 1A

Henriquez
Leiden 2333 BZ

The Netherlands
071-5685126

Wetenschappelijk

Center for Clinical Transfusion Research (Sanquin Research)
Plesmanlaan 1A

Henriquez
Leiden 2333 BZ
The Netherlands
071-5685126

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-04-2013
Aantal proefpersonen:	1600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3909
NTR-old	NTR4079
Ander register	MEC Leiden University Medical Center : P12.273
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A