

ROTEM pilot study: A new method for measuring coagulation problems in women during labor.

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In cardiac and liver surgery, the use of tromboelastometry (ROTEM) is a cost effective strategy leading to more selective substitution management and less blood transfusions. The method has not yet been validated for pregnant women nor are there...

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

Samenvatting

ID

NL-OMON20305

Bron

Nationaal Trial Register

Verkorte titel

ROTEM

Aandoening

Hemorrhage post partum

DUTCH: Haemorrhagia/Fluxus post partum

Ondersteuning

Primaire sponsor: Dr. H.C.J. Scheepers

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Overige ondersteuning: CSL Behring

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. To obtain normal 'clotting' values through ROTEM® ante partum and in the post partum period;

2. To validate these clotting values for pregnant women using conventional clotting tests as golden standard.

Toelichting onderzoek

Achtergrond van het onderzoek

Post partum hemorrhage (PPH) is the main cause of maternal death worldwide and the main cause of severe maternal morbidity in the Netherlands. The course of PPH is unpredictable. Timely recognition and prompt intervention are crucial for successful management. Crucial prognostic factors for the severity of PPH are a delay in obstetric management and development of secondary coagulopathy. In the usual care however, results of laboratory tests may take more than 60 minutes and are non specific. Therefore only in severe cases clotting tests are done and the regular management consists of transfusion of red blood cells and fresh frozen plasma. Evaluation of the efficacy of current treatment strategies is however lacking, also because of inadequate monitoring possibilities. In cardiac and liver surgery, the use of tromboelastometry (ROTEM) is a cost effective strategy leading to more selective substitution management and less blood transfusions.

Doel van het onderzoek

In cardiac and liver surgery, the use of tromboelastometry (ROTEM) is a cost effective strategy leading to more selective substitution management and less blood transfusions. The method has not yet been validated for pregnant women nor are there normal values for ROTEM in pregnancy.

Onderzoeksopzet

Gain permission from medical and ethical commission Maastricht, start trial 01-11-2010 in Maastricht and in the other centres before 01-12-2010.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pregnant, > 24+0 weeks;
2. Age $\geq$ 18 years;
3. Informed consent;
4. Mentally competent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Labor < 24+0 weeks;
2. Prophylactic or therapeutic anticoagulant therapy (carbasalate calcium within the last 10 days or low molecular weight heparins within last 48 hours).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-11-2010
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-09-2010
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	NL2407
NTR-old	NTR2515
Ander register	CCMO : ABR 32758
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A