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

No registrations found.

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

Summary

ID

NL-OMON20305

Source
NTR

Brief title
ROTEM

Health condition

Hemorrhage post partum

DUTCH: Haemorrhagia/Fluxus post partum

Sponsors and support

Primary sponsor: Dr. H.C.J. Scheepers
Postbus 5800
6202 AZ Maastricht
043-3874800
hcj.scheepers@mumc.nl
Source(s) of monetary or material Support: CSL Behring

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To evaluate whether the results of conventional clotting test or ROTEM can predict mild or severe HPP.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Pregnant, > 24+0 weeks;

2. Age ≥ 18 years;

3. Informed consent;

4. Mentally competent.

Exclusion criteria

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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-09-2010
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	NL2407
NTR-old	NTR2515
Other	CCMO : ABR 32758
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A