

# Validation of the thrombin generation assay in pregnancy

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON24748

### Source

Nationaal Trial Register

### Health condition

Women in the last trimester of their pregnancy.

## Sponsors and support

**Primary sponsor:** University Medical Center

**Source(s) of monetary or material Support:** No funding,

## Intervention

## Outcome measures

### Primary outcome

Primary outcome is a reference range for a plasma thrombin generation assay and a newly developed whole blood thrombin generation assay.

### Secondary outcome

Correlation with peri-partal bleeding.

## Study description

### Background summary

Blood of 120 pregnant women will be analysed for plasma thrombin generation and whole blood thrombin generation to create a reference range for this population.

### Study objective

Aim of the study is to receive reference ranges for a plasma and a whole blood thrombin generation assay.

### Study design

In the final trimester before delivery patients coming to the polyclinics and/or for hospital admission will be asked to participate. After informed consent 18ml citrated blood will be drawn during a regular blood drawing.

### Intervention

No intervention planned.

This study is observational.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

All healthy, adult women who are in the final trimester of their pregnancy.

### Exclusion criteria

Acquired and inherited coagulation abnormalities.

HELLP-syndrome and pre-eclampsia.

## 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:	Pending
Start date (anticipated):	17-09-2014
Enrollment:	120
Type:	Anticipated

## Ethics review

Positive opinion

Date: 11-09-2014  
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	NL4630
NTR-old	NTR4782
Other	: METC 14-4-063

## Study results

### Summary results

N. M. de Lange\*, L. E. van Rheenen-Flach, M. D. Lance´ , L. Mooyman4, M.Woiski, E. C. van Pampus,M. Porath, A. C. Bolte2, L. Smits, Y. M. Henskens and H. C. Scheepers.  
BJA-2014: Peri-partum reference ranges for ROTEM thromboelastometry