Levels of hemostasis factors after pregnancy

Published: 13-05-2009
Last updated: 14-12-2024

The aim of this study is to determine the levels of hemostasis factors after an uncomplicated pregnancy.

Ethical review	Approved WMO
Status	Completed
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON35473

Source
ToetsingOnline

Brief title
Hemostasis after pregnancy

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
increased inclination to clotting, thrombophilia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hemostasis, pregnancy

Outcome measures

Primary outcome

Concentration of hemostasis factors (Activated Protein C, protein C, protein S,

APTT, trombotest, antitrombin, factor V Leiden, protrombine, lupus

anticoagulans-test, anti-cardiolipine antibodies, von Willebrand factor)

Secondary outcome

n.a.

Study description

Background summary

In blood samples, collected 3 months after a complicated pregnancy, the levels of hemostasis factors are often abnormal and associated with thrombophilia. With repeated measures, at least 1 month later, the levels are often normalized. It is known that hemostasis factors change during pregnancy. In this project we want to study whether the abnormal levels we measure 3 months postpartum are realy abnormal or whether the observed abnormalities are the consequence of the pregnancy. If this is the case, the reference values for this group of women needs to be changed.

Study objective

The aim of this study is to determine the levels of hemostasis factors after an uncomplicated pregnancy.

Study design

2 x sampling of 10 ml blood, 3 months and 6-9 months after delivery.

Study burden and risks

minimal burden (2x venapunction)

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

uncomplicated pregnancy, age > 18 years

Exclusion criteria

complicated pregnancy (preeclampsia, HELLP-syndrome), history of repeated miscariages, growth retardation, hemostasis abnormalities

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-10-2009
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	11-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL24511.078.08