zwangerschapsuitkomsten bij vrouwen met een erfelijke stollingsziekte

No registrations found.

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

Summary

ID

NL-OMON23871

Source
Nationaal Trial Register

Brief title
PRIDES study

Health condition

von Willebrand disease
hemophilia carrier
post partum hemorrhage (PPH)

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: World Federation of Hemophilia

Intervention

Outcome measures

Primary outcome

The incidence of severe PPH, defined as 1000mL or more blood loss within the first 24 hours after delivery

Secondary outcome

The incidence of primary PPH, defined as 500mL or more blood loss within the first 24 hours after delivery

The incidence of late PPH, defined as excessive vaginal blood loss between 24 hours and 12 weeks after delivery needing hospital admission

Results of the PRO questionnaires

Study description

Background summary

‘Postpartum hemorrhage (PPH) is a major cause of maternal mortality. The PPH incidence in women with von Willebrand disease (VWD) or carriers of hemophilia is twice as high as in the normal population. The primary aim of this prospective observational cohort study is to estimate the incidence of severe PPH ≥1000 mL in women with VWD and hemophilia carriers treated according to the revised National guideline for pregnancy management of these women and exclude an unacceptable high incidence of 20%.’

Study objective

We hypothesize that the occurrence of severe post partum hemorrhage will approache the incidence in the normal population after implementation of a revised national guideline on the management of pregnancy in women with VWD or hemophilia carriers

Study design

outcome assessment at one, six and twelve weeks post delivery

Intervention

three patient reported outcome questionaires after delivery

Contacts

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Eligibility criteria

Inclusion criteria

-Ongoing pregnancy beyond 10 weeks after the last menstruation

-Carrier of hemophilia A or B or Von Willebrand disease type 1, type 2 or type 3

-Age >18 years

Exclusion criteria

-Another concomitant coagulation disorder that needs a deviation of the treatment advises according to the revised national guideline on the management of pregnancy in hemophilia carriers and von Willebrand disease

-Use of therapeutic or intermediate dose LMWH before delivery

-Inability to give informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2018
Enrollment:	135
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-01-2018
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	NL6770
NTR-old	NTR6947
Other	MEC : 13-792

Study results