Controlled hypotensive versus massive fluid resuscitation strategy: influence on blood loss and hemostatic parameters in obstetric hemorrhage

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In women with early, mild PPH (blood loss 500-750ml) we would like to establish whether restrictive resuscitation strategy reduces the progression to severe PPH (blood loss > 1000 ml) compared to care as usual

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47450

Source
ToetsingOnline

Brief title
Resuscitation strategy in obstetric hemorrhage

Condition

- Other condition
- Maternal complications of labour and delivery

Synonym
bleeding, Post partum hemorrhage

Health condition

stollingsproblemen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood loss, Coagulation, Hypotensive fluid resuscitation strategy, Post partum hemorrhage

Outcome measures

Primary outcome

In women with early, mild PPH (blood loss 500-750ml) we would like to

establish whether restrictive resuscitation strategy reduces the progression to

severe PPH (blood loss > 1000 ml) compared to care as usual

Secondary outcome

1. To evaluate if controlled hypotensive resuscitation reduces transfusion

requirements.

2. To evaluate if controlled hypotensive resuscitation leads to less

coagulopathies

Study description

Background summary

Post partum hemorrhage with high maternal morbidity and mortality is an increasing problem in the Netherlands and other developed countries. Current guidelines advise massive fluid transfusion in women with post partum hemorrhage, about two times the lost amount of blood. This advice is not based on scientific evidence and could cause problems such as acidosis, edema or coagulopathies. In trauma medicine there is increasing research about restrictive fluid resuscitation. The hypothesis is to first stop the bleeding

and then volume. These data however cannot be extrapolated to pregnant women during labor.

Study objective

In women with early, mild PPH (blood loss 500-750ml) we would like to establish whether restrictive resuscitation strategy reduces the progression to severe PPH (blood loss > 1000 ml) compared to care as usual

Study design

We want to include women who have 500-750 cc blood loss. In a general hospital population, about 15% of all women will fulfil these criteria, 5% of all women will proceed to blood loss of > 1000 cc. Since during labor informed consent cannot be obtained, all women attending the out patients clinic and who are eligible to participate in the study will be asked informed consent. Also written informed consent will be obtained. In case of more than 500 cc blood loss randomisation takes place. Participants will be randomised to care as usual: massive fluid resuscitation (control group) and controlled hypotensive resuscitation (study group). In women participating in the study, blood loss will be measured.
At this stage of 500-750 cc blood loss the study protocol starts (T1). If not already available, an intravenous line and blood testing (Hb, Ht) is regular care. Women in the study group will be resuscitated with fluids at 0.75- 1.0 times of the estimated blood loss, women in the control group will be resuscitated with fluids 1.5-2 times the amount of blood loss. In all women the first 2000 cc will consist of NaCl (0.9%), the additional fluid of colloids (Voluven).

Intervention

Restrictive fluid resuscitation

Study burden and risks

Venapunction, however this is standard care in most women with post partum hemorrhage

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Pregnant women attending the outpatient clinic
- Pregnant and delivery/labor, > 24 weeks
- Age >= 18 years
- Informed consent
- Mentally competent, understanding Dutch language

Exclusion criteria

- Labor < 24+0 weeks
-Prophylactic or therapeutic anticoagulant therapy (carbasalate calcium within the last 10 days or low molecular weight heparins within last 48 hours)
- Known congenital, coagulation disorders
- Pre-eclampsia
- Known contra-indications for liberal fluid management
- Proven placenta accreta/percreta or increta;In principle there are no circumstances in which women will be excluded after the study protocol has started. We will use an intention to treat analysis, so there will be no post-randomisation exclusions. In women with more than 1500 cc of blood loss the protocol massive blood loss will be followed. At that point the endpoint of

the study intervention has been reached.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-06-2015
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL42942.068.13

Study results

Date completed:	24-09-2019
Results posted:	06-10-2021
Actual enrolment:	251

First publication
25-06-2021