Resuscitation strategy in obstetric hemorrhage.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22968

Source
Nationaal Trial Register

Health condition

Post partum hemorrhage, restritive fluid resuscitation, coagulopathy

Sponsors and support

Primary sponsor: Maastricht Universitair Medisch Centrum
Source(s) of monetary or material Support: Maastricht Universitair Medisch Centrum

Intervention

Outcome measures

Primary outcome

In women with early, mild PPH (blood loss 500-750ml) we would like to establish whether controlled hypotensive resuscitation strategy reduces the progression to severe PPH 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

Background:

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 extrpolated to pregnant women during labor.

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 fulfill 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 and written informed consent will be obtained. Randomization takes place after written informed consent is obtained. Participants will be randomized 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.

During labor, at 500-750cc 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 1000 cc will consist of NaCl (0.9%), the additional fluid Voluven./Volulyte.

Study population:

Women attending the out patients clinic in the participating hospitals.

Primary study parameters/outcome of the study:

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 compared to care as usual.

Secundary study parameters/outcome of the study:

1. To evaluate if controlled hypotensive resuscitation reduces transfusion requirements;

2. To evaluate if controlled hypotensive resuscitation leads to less coagulopathies.

Study objective

Massive fluid resuscitation in patients with post partum hemorrhage according to current guidelines might engrave the blood loss.

Study design

Interim analysis after 50 patients in each arm.

Intervention

Restrictive fluid resuscitation: standaard care means suppletion of 1,5-2 times the amount of lost blood, in the study group 0,75-1x the amount of blood loss will be administered.

Contacts

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Eligibility criteria

Inclusion criteria

1. Pregnant women attending the outpatient clinic;

2. Pregnant and delivery/labor, > 24 weeks;

3. Age ≥ 18 years;

4. Informed consent;

5. Mentally competent, understanding Dutch language.

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);

3. Known congenital, coagulation disorders;

4. Pre-eclampsia (higher risk of low plasma volume, higher risk of volume overload).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2013
Enrollment:	250

Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL3623
NTR-old	NTR3789
Other	: 42942
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A