

TeMpOH-3

No registrations found.

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

Summary

ID

NL-OMON28238

Source

Nationaal Trial Register

Brief title

TeMpOH-3

Health condition

Prophylactic catheters, balloon catheters, embolisation, embolization, abnormal placentation, abnormally invasive placenta, accreta, increta, percreta.

Profylactische katheters, ballonkatheters, embolisatie, abnormale placentatie

Sponsors and support

Primary sponsor: Sanquin, LUMC

Source(s) of monetary or material Support: Sanquin

Intervention

Outcome measures

Primary outcome

Major obstetric haemorrhage = Obstetric haemorrhage requiring at least four units of red blood cells < 24 hours after delivery

Secondary outcome

- The total amounts of used blood products in patients: the number of transfused units of RBCs, plasma (and platelets)
- (Severe) maternal morbidity, defined as peripartum hysterectomy or need for other interventions, ICU admission and length of hospitalization.
- Complications related to the radiological interventions, and complications related to surgical procedures.
- Maternal mortality.

Study description

Background summary

Major obstetric haemorrhage (MOH) is worldwide the most important cause of severe maternal morbidity and mortality. Abnormally invasive placenta (AIP), covers placenta accreta, increta and percreta, and is considered as a severe pregnancy complication that is frequently associated with major and potentially life threatening postpartum haemorrhage. The most important risk factors for AIP include advanced maternal age, placenta praevia and previous caesarean sections or other uterine surgeries.

Prophylactic placement of catheters for intraoperative balloon occlusion or embolisation of the internal iliac artery in patients at high risk of AIP may prevent the occurrence of MOH. However, this technique is not routinely performed as there is currently too scarce evidence addressing its benefits and risks.

Objectives: To assess the effect of preoperative, prophylactic arterial catheterization on the occurrence of MOH and its sequelae in patients at high risk of AIP who undergo an elective caesarean delivery, compared to omission of this intervention.

Study design: Nationwide, retrospective cohort study.

Study population: This cohort study will be carried out in patients at high risk of abnormally invasive placenta who underwent an elective caesarean delivery between January 2008 and January 2013 in the Netherlands.

Abnormally invasive placenta covers placenta accreta, increta and percreta. In our study, women with a placenta praevia, in combination with at least one previous caesarean section, are considered as patients at high risk of AIP.

Study objective

Prophylactic radiological interventions do prevent major obstetric haemorrhage in patients at high risk of abnormally invasive placenta

Study design

none

Intervention

Profylactic radiological interventions.

Contacts

Public

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Eligibility criteria

Inclusion criteria

The study is a cohort study, carried out in patients at high risk of abnormally invasive placenta who underwent an elective caesarean delivery between January 2008 and January 2013 in the Netherlands.

Exclusion criteria

Women who had an emergency caesarean delivery.

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2014
Enrollment:	750
Type:	Anticipated

Ethics review

Positive opinion	
Date:	24-02-2014
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	NL4210
NTR-old	NTR4363
Other	n/a : n/a

Study results