Netherlands Obstetric Surveillance System

No registrations found.

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

Summary

ID

NL-OMON22753

Source
NTR

Brief title
NethOSS

Health condition

Eclampsia; Cardiac Arrest; Perimortem caesarean section; maternal morbidity; maternal mortality; INOSS; NethOSS; LEMMoN

Sponsors and support

Primary sponsor: Leids University Medical Center
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Incidence
All variables will be ascertained from anonymised photocopies from case-files and entered in a secured database.

Incidence will be calculated using the CBS data on deliveries per anum.

Secondary outcome

Putative risk factors, differences in management stratagies.

By using the control group analysis of different management stratagies will be performed.

Study description

Background summary

The NethOSS is a national registration network of severe maternal morbidity. It uses a monthly mailing card to identify cases of specific form of morbidity to ascertain incidence, putative risc factors and managemengt strategies by retriewing this data from anonymised photocopies of case files.

Study objective

Calculate the incidence of eclampsia; cardiac arrest and perimortem caesarean sectio in pregnancy or puerperium in the Netherlands.

Intervention

none. Since this is an national observational study, there are no interventions applicable.

Contacts

Public

[default]
The Netherlands

Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Eclampsia:

Any woman with convulsion(s) during pregnancy or in the first 10 days postpartum, not attributable to other causes.

Cardiac arrest:

Any pregnant women in the Netherlands identified as receiving basic life support (chest compressions and, where possible, ventilation breaths), including women who have undergone PMCS.

Amniotic fluid embolism:

IN THE ABSENCE OF ANY OTHER CLEAR CAUSE
Either:
Acute maternal collapse with one or more of the following features:

• Acute fetal compromise

• Cardiac arrest

• Cardiac rhythm problems

• Coagulopathy

• Hypotension

• Maternal hemorrhage*

• Premonitory symptoms (restlessness, numbness, agitation, tingling)

• Seizure

• Shortness of breath

* Excluding women with maternal haemorrhage as the first presenting feature in whom there

was no evidence of early coagulopathy or cardio-respiratory compromise

Or

Women in whom the diagnosis was made at post-mortem examination with the finding of fetal squames or hair in the lungs

Control group:

For every case of eclampsia, a matching control will be retriewed from the reporting hospital. Controls will be retriewed by using the hospital registrtion of deliveries. Controls a matched only of parity.

Exclusion criteria

Not meeting inclusion criteria.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 05-09-2013
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	NL3988
NTR-old	NTR4160
Other	METC LUMC : P12.216/SH/sh
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A