Training Obstetrische Spoed Teams Interventie- studie.

No registrations found.

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

Summary

ID

NL-OMON21247

Source
NTR

Brief title
TOSTI trial

Health condition

Obstetric emergencies (Obstetrische acute zorg)
Multidisciplinary team training (Multidisciplinaire teamtraining)
Simulation centre (Simulatie centrum)
MedSim

Sponsors and support

Primary sponsor: ZonMW (primary sponsor)

- Eindhoven University of Technology, Eindhoven, the Netherlands
- Department of Obstetrics and Gynaecology, Máxima Medical Centre Eindhoven-Veldhoven, the Netherlands
- MedSim (Medical Education and Simulation Centre), Máxima Medical Centre Eindhoven-Veldhoven, the Netherlands
- Faculty of Health, Medicine and Life Sciences, Maastricht University, the Netherlands
- Health insurance companies VGZ and CZ, the Netherlands
- Stimulus foundation (Europees Fonds voor Regionale Ontwikkeling) by MMC in association with TU/e and European Design Centre

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Primary outcome is the number of obstetric complications throughout the first year after the intervention. Obstetric complications will be defined as the number of neonates with perinatal asphyxia (Apgar 5-minutes <7, hypoxic ischemic encephalopathy (H.I.E.), number of newborns with damage caused by shoulder dystocia (lesion of brachial plexus, clavicle fracture), number of women with eclampsia, number of women with severe post partum haemorrhage (blood transfusion >4 packed cells), hysterectomy, embolisation), number of women with amniotic fluid embolism. These complications will be obtained from the regular obstetric recordings (with exception of damage due to shoulder dystocia and severe postpartum haemorrhage, these data will be registered separately).

Secondary outcome

- Before the start of the project indicators will be developed to evaluate patient safety, teamwork and human factors. These indicators will be registered in a subgroup of the participating hospitals.
0 Arterial umbilical pH <7.05

Study description

Background summary

Background:
There are many avoidable deaths in hospitals because the care team is not well attuned. Training in emergency situations is generally followed on an individual basis. In practice, however, hospital patients are treated by a team composed of various disciplines. To prevent communication errors, it is important to focus the training on the team as a whole, rather than on the individual. Teamtraining appears to be important in contributing toward preventing these errors. Obstetrics lends itself to multidisciplinary team training. It is a field in which nurses, midwives, obstetricians and paediatricians work together and where decisions must be made and actions must be carried out under extreme time pressure.
It is attractive to belief that multidisciplinary team training will reduce the number of errors in obstetrics. The other side of the medal is that many hospitals are buying expensive patient simulators without proper evaluation of the training method.
In the Netherlands many hospitals have 1,000 or less annual deliveries. In our small country it might therefore be more cost-effective to train obstetric teams in medical simulation centres with well trained personnel, high fidelity patient simulators, and well defined training programmes.

Methods/design:
The aim of the present study is to evaluate the cost-effectiveness of multidisciplinary team training in a medical simulation centre in the Netherlands to reduce the number of medical errors in obstetric emergency situations. We plan a multicentre randomised study with the centre as unit of analysis. Obstetric departments will be randomly assigned to receive multidisciplinary team training in a medical simulation centre or to a control arm. To show a reduction in perinatal asphyxia of 40% (from 1% to 0.6%) two groups of more than 8,000 patients are necessary. Primary outcome is the number of obstetric complications throughout the first year period after the intervention. If multidisciplinary team training appears to be effective a cost-effective analysis will be performed.

Discussion:
If multidisciplinary team training appears to be effective, this training should be implemented in extra training for gynaecologists.

The Netherlands.

Study objective

There are many avoidable deaths in hospitals because the care team is not well attuned. Training in emergency situations is generally followed on an individual basis. In practice, however, hospital patients are treated by a team composed of various disciplines. To prevent communication errors, it is important to focus the training on the team as a whole, rather than on the individual. Team training appears to be important in contributing toward preventing these errors. Obstetrics lends itself to multidisciplinary team training. It is a field in which nurses, midwives, obstetricians and paediatricians work together and where decisions must be made and actions must be carried out under extreme time pressure.
It is attractive to belief that multidisciplinary team training will reduce the number of errors in obstetrics. The other side of the medal is that many hospitals are buying expensive patient simulators without proper evaluation of the training method.
In the Netherlands many hospitals have 1,000 or less annual deliveries. In our small country it might therefore be more cost-effective to train obstetric teams in medical simulation centres with well trained personnel, high fidelity patient simulators, and well defined training programmes.

The aim of the present study is to evaluate the cost-effectiveness of multidisciplinary team training in a medical simulation centre in the Netherlands to reduce the number of medical errors in obstetric emergency situations.

Study design

Data (the number of obstetric complications) will be collected one year after the intervention.

Intervention

The intervention group will have multidisciplinary team training in a medical simulation centre. These team trainings are given by specially trained instructors and facilitators (gynaecologists, anaesthesiologists, emergency care doctors, midwives, educationalists, medical engineers and psychologists). All instructors and facilitators are trained in crew resource management.
The control group will not have multidisciplinary team training in a medical simulation centre.

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Eligibility criteria

Inclusion criteria

Teaching and non-teaching hospitals in the Netherlands which do not have frequently multidisciplinary team training.

Exclusion criteria

Hospitals which already have frequently multidisciplinary team training for its care workers.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL1749
NTR-old	NTR1859
Other	ZonMW : 170992303
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A