Post-traumatic stress disorder (PTSD) in women and their partners, following severe post-partum hemorrhage.

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A prospective evaluation in a hospital setting on the frequency of post-traumatic stress disorder (PTSD) and post-traumatic stress (PTS) symptoms, following a severe post-partum hemorrhage (PPH) of 2,0 liters or more, compared to deliveries without...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anxiety disorders and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON42028

Source
ToetsingOnline

Brief title
PTSD in women and their partners, following post-partum hemorrhage.

Condition

- Anxiety disorders and symptoms

Synonym
post-traumatic stress disorder, psychotrauma, shell shock

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Teaching hospital en Anna Paviljoen van het OLVG

Intervention

Keyword: hemorrhages, post-partum, PTSD, traumatic

Outcome measures

Primary outcome

1. PTSD diagnosis

2. No PTSD diagnosis

Secondary outcome

1. Post-traumatic stress symptoms (based on DSM-5 criteria of PTSD)

B: Intrusion

C: Avoidance

D: Negative cognitions and mood

E: Hyper arousal

F: Duration symptoms

G: Functional significance/influence on life

Co-morbidity: alcohol, drug, medication abuse

Search for psychological treatment

2. No post-traumatic stress symptoms

Study description

Background summary

Post-traumatic stress disorder (PTSD) is an anxiety disorder resulting from exposure to an event that is considered as traumatic. PTSD symptoms are intrusion, avoidance, negative cognitions and mood, and hyper arousal, as described by the DSM-5. It was first described and is best known in relation to war traumas, but is now also recognized in relation to any potential traumatic event. For example, it was shown that a near death experience during cardiac

arrest can lead to PTSD. Also, the form of exposure to the event may differ, both victims as well as spectators can develop PTSD. The life time prevalence of PTSD in the Netherlands is 7.4%.

Previous studies have shown a PTSD prevalence in women as a result of traumatic childbirth between 0.0 * 5.9 % worldwide, and 1.0- 3.0% in Western countries. A large study in the Netherlands showed a 1.2% prevalence rate, which is around 2000 women per year.

Witnesses of traumatic birth, such as partners and health care providers, also have a risk of developing PTSD and depression. Several studies have been done to explore obstetrical and patient characteristic risk factors in partners. Although there is a lack of good qualitative and quantitative studies, the prevalence of PTSD is estimated between 0,0 and 5,0% 6 weeks post-partum. One Dutch study showed that symptoms of depression and PTSD during the pregnancy experienced by the woman, give a higher risk of the partner developing PTSD and depression after birth complications, such as pre-eclampsia or preterm prelabor rupture of membranes (PPROM). However, the common idea of the prevalence, risk factors and treatment for PTSD and PTS-symptoms in partners and health care providers needs further investigation. Our clinical experience is that partners often experience a sense of uncertainty and powerlessess, when confronted with the emergency situation of a PPH.

The definition of a severe PPH is usually blood loss of 2,0 liters or more, but differs internationally. For example, it is sometimes defined as a hemorrhage that resulted in a blood transfusion of 4 packed cells or more, or resulted in an embolization or hysterectomy. The incidence rate of severe PPHs in the Netherlands is 4.5 per 1000 deliveries. Severe PPH can result in extremely low blood pressure, lethargy, dyspnea, anuria, and eventually collapse and death.

The most common causes for PPH are uterine atony, retained placenta, vaginal and cervical tears, placenta praevia and coagulation deficits. Patients often experience severe PPH as traumatic, describing it as if they were slowly bleeding to death. Severe hemorrhages of 2,0 liters or more often lead to emergency situations, whereby women may have a higher risk of developing PTSD, because the PPH is accompanied by physical symptoms.

Study objective

A prospective evaluation in a hospital setting on the frequency of post-traumatic stress disorder (PTSD) and post-traumatic stress (PTS) symptoms, following a severe post-partum hemorrhage (PPH) of 2,0 liters or more, compared to deliveries without a PPH, both in patients as well as in their partners. When PPHs show to be a risk factor for PTSD, this may lead to more intensive follow-up and screening for PTSD in PPH patients in the future.

Study design

This will be a prospective cohort study. First, patients and controls are selected from the complication and birth registers in 10 hospitals by designated investigators from each hospital. When patients leave the hospital, they receive a short information letter, to inform them that they will be invited for participation 6 to 8 weeks after birth. This information does not include the content of the research.

The address, phone number and native language of the women are available in the hospital registers. Since information of partners is usually lacking, a letter is sent to their home address, addressing both patient and partner in the same letter. If they are non-Dutch speaking patients, they will receive the letters and forms in English. This is done 6 weeks after delivery. They are informed about our study by a patient letter and asked to participate. Attached there will be two separate informed consents and envelopes; one for the patient and one for the partner, the same applies for the control patients and partners. When they sign this form, they agree to participate in our research (see informed consent). A separate question is added for women that do not want to participate, asking for permission to use their medical details, so we can include their partner. We also ask to fill in both their e-mail addresses and phone numbers. After we receive their informed consent, patient, partner and controls will receive separate e-mails. This e-mail contains a link to the website of Surveymonkey with a digital version of the PCL-5 questionnaire. A first (1 week) and second (2 weeks) reminder will be sent to non-responders through e-mail.

When a patient scores above our cut off values on the questionnaire, they will be contacted by phone for a telephone interview. The interview will be the Clinician Administered PTSD Scale for DSM-5 (CAPS -5), which is the golden standard for the diagnosis of PTSD. The CAPS-5 is available in Dutch and English, and both versions are currently being validated. Cut off values will be based on these studies. Through this interview, the diagnosis of PTSD or PTS symptoms is either confirmed or rejected.

Study burden and risks

Taking part in the survey means patients have to fill in a questionnaire and do a telephone interview. This questions may trigger post-traumatic stress symptoms, which may be experienced as a burder for patients with PTSD. However, this is a small risk, as patients can choose to pauze or even quit the survey at any time. When a patient scores above our cut-off values, they are offered help through their general practitioner (GP). Their GP is informed about the result of our test and are advised to refer their patient to a specialized psychologist. This may be beneficial for the course of their potential

disorder. Approval of the patient is asked in the informed consent.

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

Group 1 (women):
18 years older
Post-partum hemorrhage of 2,0 liters or more ;Group 2 (partners):
18 years or older
Partner of group 1.1 patient/permission of patient for medical history
Witnessed hemorrhage

Exclusion criteria

Group 1 (women):
Medical history of post-traumatic stress disorder
Inability to speak or read Dutch or English;Group 2 (partner):
Medical history of post-traumatic stress disorder
Inability to speak or read Dutch or English

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	27-01-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-07-2015

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29566
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL50273.100.14
OMON	NL-OMON29566