Herstel na een baarmoederoperatie: Onderzoek naar beïnvloedende factoren.

No registrations found.

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

Summary

ID

NL-OMON29604

Source
Nationaal Trial Register

Brief title
Hysterectomy&CPSP

Health condition

Patients undergoing elective hysterectomy.
Baarmoederverwijdering

Sponsors and support

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Intervention

Outcome measures

Primary outcome

Chronic pain after surgery: Brief pain inventory – short form (BPI-SF) and DN4.

Secondary outcome

1. Physical functioning (SF-36);

2. Global Surgical Recovery (GSR);

3. Depression (CES-D);

4. Optimism (LOTr);

5. General well-being (W-BQ12);

6. Sexual functioning (FSFI).

Study description

Background summary

The prevalence of chronic postoperative pain (CPSP) after hysterectomy ranges from 5 up to 32%.

Etiologic/prognostic research on postoperative recovery traditionally focussed on surgical and anesthesiological factors.

This prospective, observational, multicenter study aims to assess influencing factors for postoperative recovery in a wider perspective.

Apart from somatic factors the interaction between genotype and psychological factors like optimism and resilience will be assessed. Whether surgical intervention leads to epigenetic changes will be studied as well. Finally, the effect of the immunologic response on recovery will be studied.

Primary outcome measure:

Chronic postsurgical pain.

Secondary outcome:

Physical and psychological recovery, sexual functioning.

Population:

500 woman (18-65 years) undergoing elective hysterectomy for benign indication.

Baseline data 1 week before surgery, data during hospital stay day 0-4.

Follow-up at 3 and 12 months postoperative.

Study objective

Primary Objective:

The identification of (somatic and psychological) risk and protective factors for postoperative recovery, including the development of chronic post operative pain (CPSP), defined as persistent pain 3 and 12 months after the intervention.

Secondary Objective(s):

1. Determination of the prevalence of CPSP after hysterectomy;

2. Determination of the prevalence of sexual dysfunctions after hysterectomy;

3. The identification of risk and protective factors for sexual dysfunctions after hysterectomy;

4. Exploration of the mechanisms (behavioural, cognitive, biological) of CPSP.

Study design

1. Baseline: 1 week before surgery;

2. Day of surgery - Day 4 after surgery;

3. 3 Months after surgery;

4. 12 Months after surgery.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Age 18 – 60 years;

2. Good command of Dutch language;

3. Elective surgery (in azM Maastricht; CzE Eindhoven; MMC Veldhoven/Eindhoven);

4. Total or subtotal hysterectomy, with or without oophorectomy;

5. Vaginal or abdominal hysterectomy;

6. Laparotomy and laparoscopy;

7. Informed consent.

Exclusion criteria

1. Cancer;

2. Illiteracy;

3. Cognitive impairment (as indicated in the medical record).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2010
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-01-2011
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	NL2576
NTR-old	NTR2702
Other	MEC Maastricht University : 10-05-001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A