Herstel na een baarmoederoperatie: Onderzoek naar beïnvloedende factoren.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29604

Bron
NTR

Verkorte titel
Hysterectomy&CPSP

Aandoening

Patients undergoing elective hysterectomy.
Baarmoederverwijdering

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Baseline: 1 week before surgery;

2. Day of surgery - Day 4 after surgery;

3. 3 Months after surgery;

4. 12 Months after surgery.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cancer;

2. Illiteracy;

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-09-2010
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-01-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2576
NTR-old	NTR2702
Ander register	MEC Maastricht University : 10-05-001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A