Laparoscopy versus laparotomy in treatment of early stage endometrial cancer: a multi-centre cost-effectiveness study.

Gepubliceerd: 20-11-2006 Laatst bijgewerkt: 18-08-2022

The laparoscopic approach is a cost-effective and safe alternative to laparotomy in early stage endometrial cancer patients with less major complications in the laparoscopy group.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22764

Bron
NTR

Verkorte titel
TLH-RCT

Aandoening

Endometrioid adenocarcinoma grade 1, or 2, clinically stage I disease, negative endocervical curettage or -biopsy

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Our main outcome is the rate of major complications, being an indicator of clinically relevant treatment related morbidity. Major complications considered are: injuries of bowel, bladder, ureter, vessel, nerves; thrombo-embolic events such as deep venous thrombosis or pulmonary embolism; haematoma requiring surgical intervention; haemorrhage requiring transfusion and/or surgical intervention; wound dehiscence requiring surgical intervention or re-admission; wound infections including vaginal vault abscess, requiring surgical intervention and/or prolonged hospital stay and/or readmission and/or treatment; other major complications.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: Comparison of treatment related morbidity and cost-effectiveness in early stage endometrial cancer patients treated by laparoscopy (total laparoscopic hysterectomy and bilateral salpingo-oophorectomy (TLH+BSO)) versus laparotomy (the standard approach by total abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH+BSO) through a vertical abdominal midline incision). Study design: A multicentre prospective randomized clinical phase 3 trial (RCT) (including at least 15 centres). After inclusion and informed consent 275 patients will be randomized to laparoscopy or laparotomy (2:1). Standardized care regarding anticoagulants and antibiotics is provided. The gynecologist will record outcomes on a structured case record form (CRF). These CRF's will be checked by the research nurse afterwards. Patients will be asked to fill in questionnaires pre-operatively, after 6 weeks, 3 and 6 months. Study population: Inclusion criteria: Patients with early stage endometrial cancer (endometrioid adenocarcinoma grade 1 or 2, clinically stage I disease, negative endocervical curettage or biopsy), signed written informed consent, age 18 years and older. Before participating in the study of each participating gynecologist the laparoscopic skills in performing a TLH will be assessed by an experienced visiting gynecologist using a structured evaluation form. Only gynecologists with a sufficient score (>= 28 points) on an OSATS (Objective Structured Assessment of Technical Skills) form will be allowed to participate.
Exclusion criteria: other histological types than grade 1 or 2 endometrioid adenocarcinoma, clinically advanced disease (stage II to IV), uterine size larger than 10 weeks gestation and cardio pulmonary contra indications for laparoscopy. Intervention: Laparoscopy (TLH+BSO) compared to the standard approach by laparotomy (TAH+BSO) through a vertical abdominal midline incision. Outcome measures: Our main outcome is the rate of major complications, being an indicator of clinically relevant treatment related morbidity. Secondary outcome measures are: 1) Costs and cost-effectiveness 2) Minor complications. 3) Quality of life.

Doel van het onderzoek

The laparoscopic approach is a cost-effective and safe alternative to laparotomy in early stage endometrial cancer patients with less major complications in the laparoscopy group.

Onderzoeksproduct en/of interventie

Laparoscopy (TLH+BSO) compared to the standard approach by laparotomy (TAH+BSO) through a vertical abdominal midline incision.

Contactpersonen

Publiek

University Medical Center Groningen (UMCG), Department of Gynaecology,
Hanzeplein 1
Claudia B.M. Bijen
Groningen 9700 RB
The Netherlands
+31 (0)50 3611528

Wetenschappelijk

University Medical Center Groningen (UMCG), Department of Gynaecology,
Hanzeplein 1
Claudia B.M. Bijen
Groningen 9700 RB
The Netherlands
+31 (0)50 3611528

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with early stage endometrial cancer (endometrioid adenocarcinoma grade 1 or 2, clinically stage I disease, negative endocervical curettage);

2. Signed written informed consent;

3. Age 18 years and older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Other histological types than grade 1 or 2 endometrioid adenocarcinoma;

2. Clinically advanced disease (stage II to IV);

3. Uterine size larger than 10 weeks gestation;

4. Cardio pulmonary contra indications for laparoscopy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2007
Aantal proefpersonen:	275
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-11-2006
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	NL808
NTR-old	NTR821
Ander register	: N/A
ISRCTN	ISRCTN49542560

Resultaten

Samenvatting resultaten
N/A