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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22764

Source
NTR

Brief title
TLH-RCT

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Costs and cost-effectiveness;
2. Minor complications;
3. Quality of life, sexual functioning, body image and VAS pain.

Study description

Background summary

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.

Study objective

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.

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2007
Enrollment:	275
Type:	Actual

Ethics review

Positive opinion

Date:	20-11-2006
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	NL808
NTR-old	NTR821
Other	: N/A
ISRCTN	ISRCTN49542560

Study results

Summary results
N/A