

# Laparoscopy versus laparotomy in treatment of early stage endometrial cancer: a multicentre cost-effectiveness study

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

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

### Acronym

TLH-RCT

### Study objectives

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.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approval received from the Medical Ethical Committee of the University Medical Center Groningen on the 31st May 2006 (ref: M06..38223).

### Study design

Randomised controlled, parallel group, single blinded, multicentre trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Endometrial carcinoma

### Interventions

Laparoscopy (Total Laparoscopic Hysterectomy [TLH] and Bilateral Salpingo-Oophorectomy [BSO]) compared to the standard approach by laparotomy (Total Abdominal Hysterectomy [TAH] and BSO) through a vertical abdominal midline incision.

### Intervention Type

Other

**Phase**

Not Specified

**Primary outcome measure**

Our main outcome is the rate of major complications, being an indicator of clinically relevant treatment related morbidity. Major complications considered are:

1. Injuries of bowel, bladder, ureter, vessel, nerves
2. Thrombo-embolic events such as deep venous thrombosis or pulmonary embolism
3. Haematoma requiring surgical intervention
4. Haemorrhage requiring transfusion and/or surgical intervention
5. Wound dehiscence requiring surgical intervention or re-admission
6. Wound infections including vaginal vault abscess, requiring surgical intervention and/or prolonged hospital stay and/or readmission and/or treatment
7. Other major complications

**Secondary outcome measures**

1. Costs and cost-effectiveness
2. Minor complications
3. Quality of life, sexual functioning, body image and Visual Analogue Scale (VAS) pain

**Overall study start date**

01/01/2007

**Completion date**

01/01/2010

**Eligibility****Key inclusion criteria**

1. Patients with early stage endometrial cancer (endometrioid adenocarcinoma grade one or two, clinically stage I disease, negative endocervical curettage)
2. Signed written informed consent
3. Age 18 years and older

**Participant type(s)**

Patient

**Age group**

Not Specified

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

275

**Total final enrolment**

**Key exclusion criteria**

1. Other histological types than grade one or two endometrioid adenocarcinoma
2. Clinically advanced disease (stage II to IV)
3. Uterine size larger than ten weeks gestation
4. Cardio pulmonary contra indications for laparoscopy

**Date of first enrolment**

01/01/2007

**Date of final enrolment**

01/01/2010

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

University Medical Center Groningen (UMCG)

Groningen

Netherlands

9700 RB

**Sponsor information****Organisation**

University Medical Center Groningen (UMCG) (The Netherlands)

**Sponsor details**

P.O. Box 30001

Groningen

Netherlands

9700 RB

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.rug.nl/umcg/index?lang=en>

**ROR**

<https://ror.org/03cv38k47>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## Alternative Name(s)

Netherlands Organisation for Health Research and Development

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

Netherlands

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2011	14/01/2021	Yes	No