

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

Submission date 28/12/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 28/12/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/01/2021	Condition category Cancer	☐ 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

Protocol serial number
NL808, NTR821

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).

Primary study design

Interventional

Study design

Randomised controlled, parallel group, single blinded, multicentre trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 Years

Sex

Not Specified

Total final enrolment

279

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)

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

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?
Results article	results	01/04/2011	14/01/2021	Yes	No