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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/12/2006	**Overall study status** Completed	
Last Edited 14/01/2021	**Condition category** Cancer	

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

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).

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

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)

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