Recurrence and Survival after laparoscopy versus laparotomy in early-stage endometrial cancer: Follow-up five years after a randomised trial

No registrations found.

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

Summary

ID

NL-OMON25179

Source
Nationaal Trial Register

Brief title
TLH-TAH follow-up study

Health condition

Endometrial cancer

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Disease-free survival

Secondary outcome

Site of primary recurrence, overall survival and disease-specific survival

Study description

Background summary

This is a follow-up study of the Dutch randomised controlled, multi-centre TLH-TAH trial. Women with clinically stage I, low-grade endometrial cancer were randomized on a 2:1 basis either to TLH or TAH without lymphadenectomy. Aim was to provide the long-term survival outcomes. The current study used five-years follow-up data collected from the 19 participating centres. Our primary hypothesis was that a TLH is equally safe with respect to five-years disease-free survival outcomes in comparison to a TAH.

Study objective

Total laparoscopic hysterectomy is equally safe with respect to five-years disease-free survival outcomes in comparison to a total abdominal hysterectomy

Study design

Five years

Intervention

Total laparoscopic hysterectomy versus total abdominal hysterectomy

Contacts

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Eligibility criteria

Inclusion criteria

Participants included in the initial TLH-TAH study. They previously included women with histologically proven grade 1-2 endometrioid adenocarcinoma or complex atypical hyperplasia, clinically confined to the uterin corpus (ie, clinical stage I).

Exclusion criteria

Exclusion criteria of the initial TLH-TAH study: any non-endometrioid adenocarcinoma histological types, uterine size larger than that expected at 12 weeks of pregnancy, and cardiopulmonary contraindications for laparoscopy of laparotomy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	279
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description

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Ethics review

Positive opinion

Date:	22-11-2020
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	NL9097
Other	University Medical Center Groningen : NTR821

Study results

Summary results

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