STATEC: A randomised trial of non-selective versus selective adjuvant therapy in high risk endometrial cancer

Published: 29-09-2014
Last updated: 21-04-2024

To determine the clinical effectiveness of adjuvant therapy given to all unstaged (no lymph node dissection) high risk stage 1 endometrial cancer, compared with only node positive (staged) cases as judged by full lymph node dissection.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41132

Source
ToetsingOnline

Brief title
STATEC

Condition

- Reproductive neoplasms female malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
cancer of the uterus, Endometrial cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KWF kankerbestrijding;Cancer Research UK

Intervention

Keyword: Adjuvant therapy, Endometrial cancer, Lymphadenectomy

Outcome measures

Primary outcome

Overall survival

Secondary outcome

Progression-free survival

Side effects:

- of surgery (using Dindo classification)

- of chemotherapy/radiotherapy (using NCI common terminology for adverse events)

Quality of life (EORTC QLQ C-30 and EN24 module voor endometrial cancer)

Cost effectiveness ((EQ-5D-5L)

Study description

Background summary

Endometrial cancer is the most common gynaecological cancer in the Netherlands. Primary surgical treatment consists of hysterectomy and bilateral salpingo-oophorectomy (BSO). Controversy exists over the use of lymph node staging and the effectiveness of adjuvant treatment in patients with a high risk of recurrence. Without lymph node dissection, clinicopathological prognostic factors are used to select adjuvant treatment and all women with high risk of recurrent disease will be offered further treatment. This study will demonstrate the optimal surgical treatment and use of adjuvant therapy for women with high risk stage 1 endometrial cancer, resulting in elimination of the wide variation in practice across developed countries.

Study objective

To determine the clinical effectiveness of adjuvant therapy given to all unstaged (no lymph node dissection) high risk stage 1 endometrial cancer, compared with only node positive (staged) cases as judged by full lymph node dissection.

Study design

Randomised, non-inferiority multicentre trial. Patients will be recruited in the Unites States, United Kingdom, Australia, New Zealand and the Netherlands. Patients will be randomised over two study-groups.

Intervention

Subjects will be randomised to have hysterectomy with BSO plus either staging with a systematic pelvic and para-aortic lymph node dissection, or no node dissection. All women in the unstaged arm will receive adjuvant therapy due to the risk of node involvement and/or relapse of 15-20%. In the staged arm, only women with positive nodes will receive adjuvant therapy.

Study burden and risks

The STATEC trial will address the ongoing international debate regarding lymphadenectomy for the treatment of high risk endometrial cancer. The two strategies to be investigated in this trial represent the two most widely accepted, and most frequently performed treatment options. Consequently, patients in this trial will not face any new risks compared to standard treatment. All follow-up procedures will be performed during regular follow-up appointments. Patients with negative nodes will not receive chemotherapy/radiation and therefore will not face the well known side effects associated with this standard adjuvant treatment. We acknowledge that there may be a very small chance that these patients, who have not undergone adjuvant therapy, may face an increased risk of recurrence of the disease. Frequent check-ups will ensure rapid detection and intervention if necessary

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histologically confirmed grade 3 endometrial carcinoma, serous, clearcell or carcinosarcoma
- Grade 2 endometrioid carcinoma if LVSI is confirmed on histology, or deep invasion into the myometrium is demonstrated at preoperative MRI, or post operative hysterectomy specimen if randomisation is occuring at this point
- Surgery performed within 5 weeks of randomisation
- Written informed consent
- No prior anticancer therapy for endometrial cancer
- ECOG status 0-2
- No concomitant cancer
- Life expectancy of at least 3 months
- Age 18 and above
- Adequate renal, hepatic and bone marrow function
- Adjuvant treatment to commence within 8 weeks of surgery
- Willingness to complete Quality of Life Questionnaires

Exclusion criteria

- Grossly enlarged nodes on pre operative scanning
- Metastatic disease seen outside the uterus on pre operative scanning
- Separate malignancy in last 5 years

- Small cell carcinoma with neuroendocrine differentiation
- Concurrent cancer therapy
- Previous or concurrent malignant disease except carcinoma in situ of cervix, or non-melanoma skin cancer and basal cell carcinoma.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	29-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL49874.042.14