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

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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 fulllymph 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-OMON46816

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

Progressien-free survival

Distribution of pelvic and extra-pelvic relapse

Surgical side effects

Cost effectiveness

Two side studies will be conducted aimed at:

1) Quality of life

2) The diagnostic performance of sentinel lymph node procedure compared to

lymphadenectomy

Study description

Background summary

Endometrial cancer is the most camman 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 wamen with high risk of recurrent disease will be affered further treatment. This study will demonstrata the optimal surgical treatment and use of adjuvant therapy for wamen with high risk stage 1 endometrial cancer, rasuiting in eliminatien of the wide variatien in practica 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 fulllymph node dissection.

Study design

Randomised, non-inferiority multicentre trial. Patients will be recruited in the 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-aartic lymph node dissection, or na node dissection. All wamen in the unstaged arm will receive adjuvant therapy due to the risk of node invalvament and/or relapse of 15-20%. In the staged arm, only wamen 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 reprasent 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 fellow-up procedures will be performed during regular fellow-up appointments. Patients with negative nodes will not receive chemotherapyfradiation and therefore will not face the well known side effects associated with this standard adjuvant treatment. When deamed necessary these patients will receive adjuvant treatment with vaginal brachytherapy to reduce the risk on a recurrence as much as possible. Frequent check-ups will ensure rapid dateetion and intervention if necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Histologically confirmed FIGO grade 3 endometrioid or mucinous carcinoma or high grade serous, clearcell, undifferentiated or dedifferentiated carcinoma or mixed cell adenocarcinoma or carcinosarcoma
- Surgery performed within 5 weeks of randomisation
- Written informed consent
- No prior anticancer therapy for endometrial cancer
- ECOG status 0-2
- Life expectancy of at least 3 months
- Age 18 and above
-Adequate renal, hepatic and bene marrow tunetion
- Adjuvant treatment to commence within 8 weeks of surgery

- Willingness to complete Quality of Life Questionnaires

Exclusion criteria

- Grossly enlarged nodes (1Omm or largeronshort axis) 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, basal cell carcinoma and melanoma in situ.

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:	07-12-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	15-02-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT02566811
CCMO	NL63569.042.17

Study results

Summary results
Trial never started