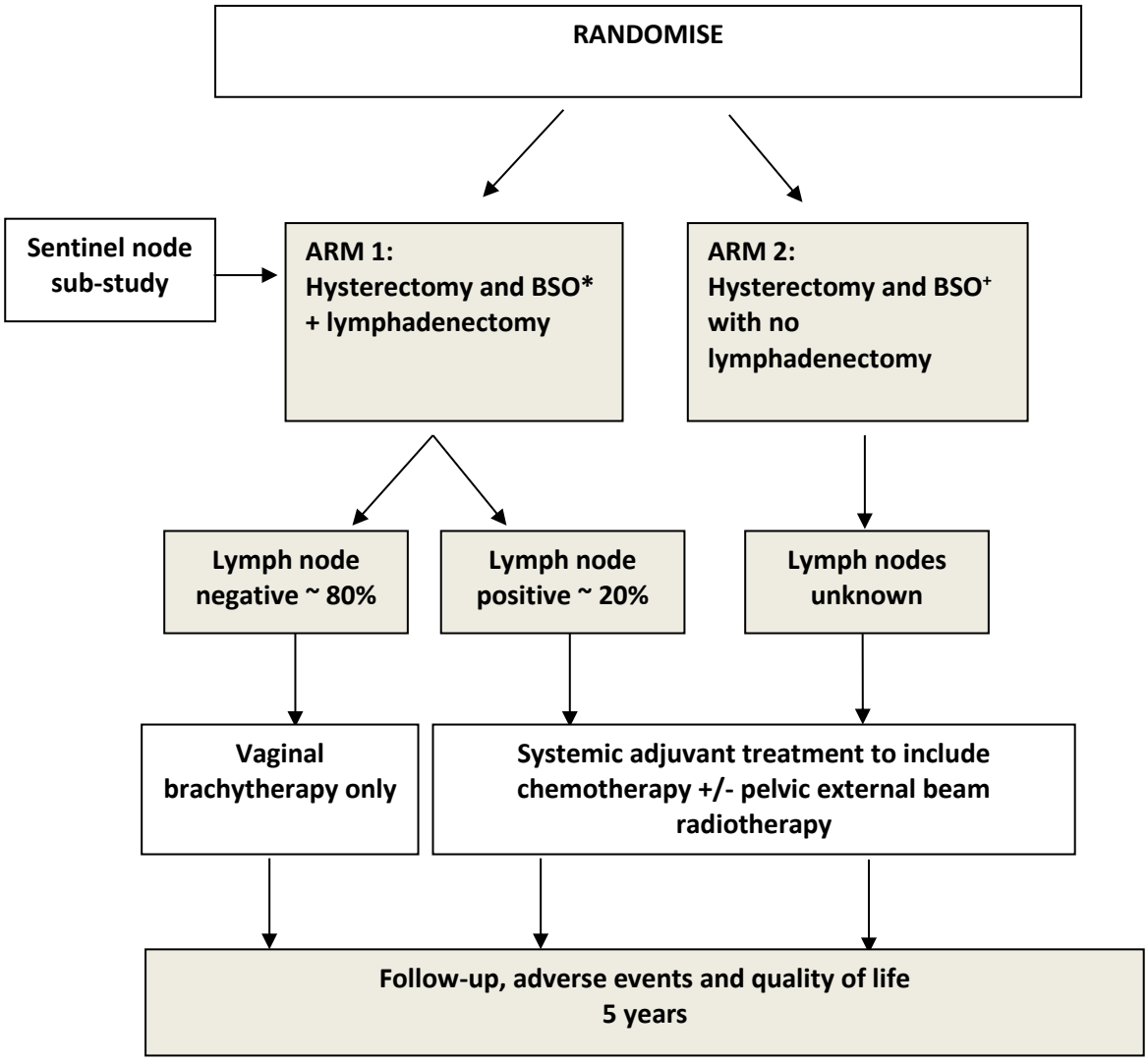
STATEC

Selective Targeting of Adjuvant Therapy for Endometrial Cancer

Full title: A randomised trial of non-Selective versus selective adjuvant Therapy in high risk Apparent sTage 1 Endometrial Cancer **(STATEC)**

Histologically confirmed high risk apparent FIGO stage I endometrial cancer based on diagnostic endometrial sampling OR hysterectomy and BSO specimen if randomisation occurring after hysterectomy and BSO:

- **FIGO grade 3 endometrioid or mucinous**
- **High grade serous, clear cell, undifferentiated or dedifferentiated carcinoma or mixed cell adenocarcinoma or carcinosarcoma**



*Lymphadenectomy alone if randomisation occurs after hysterectomy and BSO

+No further surgery if randomisation occurs after hysterectomy and BSO

STATEC

Selective Targeting of Adjuvant Therapy for Endometrial Cancer

Aim: To determine whether lymphadenectomy, used to restrict adjuvant therapy (other than vaginal brachytherapy) to node positive women, results in a non-inferior survival as compared to adjuvant therapy given to all women with high risk apparent stage 1 endometrial cancer

Primary Endpoint
Overall survival measured from the date of randomisation until the date of death from any cause

Secondary Endpoints

- Disease-free survival measured from the date of randomisation until date of first recurrence, a new secondary tumour or death from any cause, whichever occurs first
- Endometrial cancer-event free survival measured from the date of randomisation until recurrence or death from endometrial cancer, or treatment related deaths, whichever occurs first
- Endometrial cancer-specific survival measured from the date of randomisation until death from endometrial cancer, or treatment-related deaths
- Pelvic and extra-pelvic relapse-free survival as assessed by radiological imaging at time of relapse with documentation of site/s of relapse
- Cost effectiveness using the EQ-5D-5L for economic evaluation
- Surgical adverse events (acute and late) as assessed by the Common Terminology Criteria for Adverse Events v4.03

Key endpoints in the two sub-studies

- Patient reported Quality of Life as measured using validated questionnaires (i) EORTC QLQ-C-30 and the endometrial cancer module QLQ-EN24 (ii) additional items from other EORTC cancer modules: QLQ-OV28 (items 52-54), QLQ-CX24 (items 41, 43, 44), QLQ-PR29 PR25 (items 39-40) and (iii) Self-report lower-extremity lymphoedema screening questionnaire.
- Accuracy, sensitivity and specificity (i.e. diagnostic performance) of SLN, and the ratio of sensitivity to false positive rate (called likelihood ratio).

CONTACT DETAILS: STATEC Trial Co-ordinator: ctc.STATEC@ucl.ac.uk; Tel: 020 7679 9872;
Cancer Research UK & UCL Cancer Trials Centre, 90 Tottenham Court Road, London W1T 4TJ

Inclusion Criteria – Summary

- Histologically confirmed high risk apparent FIGO stage I endometrial cancer:
  - FIGO grade 3 endometrioid or mucinous carcinoma
  - High grade serous, clear cell, undifferentiated or de-differentiated carcinoma or mixed cell adenocarcinoma or carcinosarcoma
- Surgery to be performed ≤ 5 weeks after randomisation
- No prior anticancer therapy for endometrial cancer
- ECOG performance status 0-2
- Life expectancy > 3 months
- Age ≥ 16 years
- Adjuvant treatment to commence ≤ 8 weeks after surgery
- Willingness to complete QOL questionnaires

Exclusion Criteria – Summary

- Grossly enlarged node(s) on baseline radiological imaging
- Invasion of the cervical stroma on baseline radiological imaging or obvious cervical disease on clinical examination
- Involvement of uterine serosa or metastatic disease seen outside the uterus on baseline radiological imaging
- Small cell carcinoma with neuroendocrine differentiation

Assessments - Summary

Baseline: Endometrial sampling (diagnostic or surgical), physical exam (inc vaginal), CT/MRI abdomen pelvis, CT-Xray chest, transvaginal ultrasound (optional), ECOG PS, blood test, AEs, QOL & EQ-5D

- Follow up: vaginal exam, ECOG PS, abdominal and pelvic imaging as above where indicated, AEs, QOL and EQ-5D

Sample Collection

- Tissue blocks from hysterectomy plus any lymph nodes
- 1 x baseline whole blood sample