

**Selective Targeting of Adjuvant
Therapy for Endometrial Cancer-
STATEC**

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Hypotheses

- ▶ Lymphadenectomy is not independently therapeutic
- ▶ Improvement in survival may require systemic therapy
- ▶ Tailoring adjuvant therapy based on node status may limit toxicity with equal survival
- ▶ Sentinel node biopsy may be as effective as full LND to triage patients to adjuvant therapy



Design

- ▶ All patients should be high-risk (> 15-20% node positive)
- ▶ Adjuvant therapy should be used in node positive women and those with nodes unknown
- ▶ No adjuvant therapy in node negative pts
- ▶ Sentinel node biopsy incorporated in LND arm
- ▶ Primary endpoint OS; powered for non-inferiority

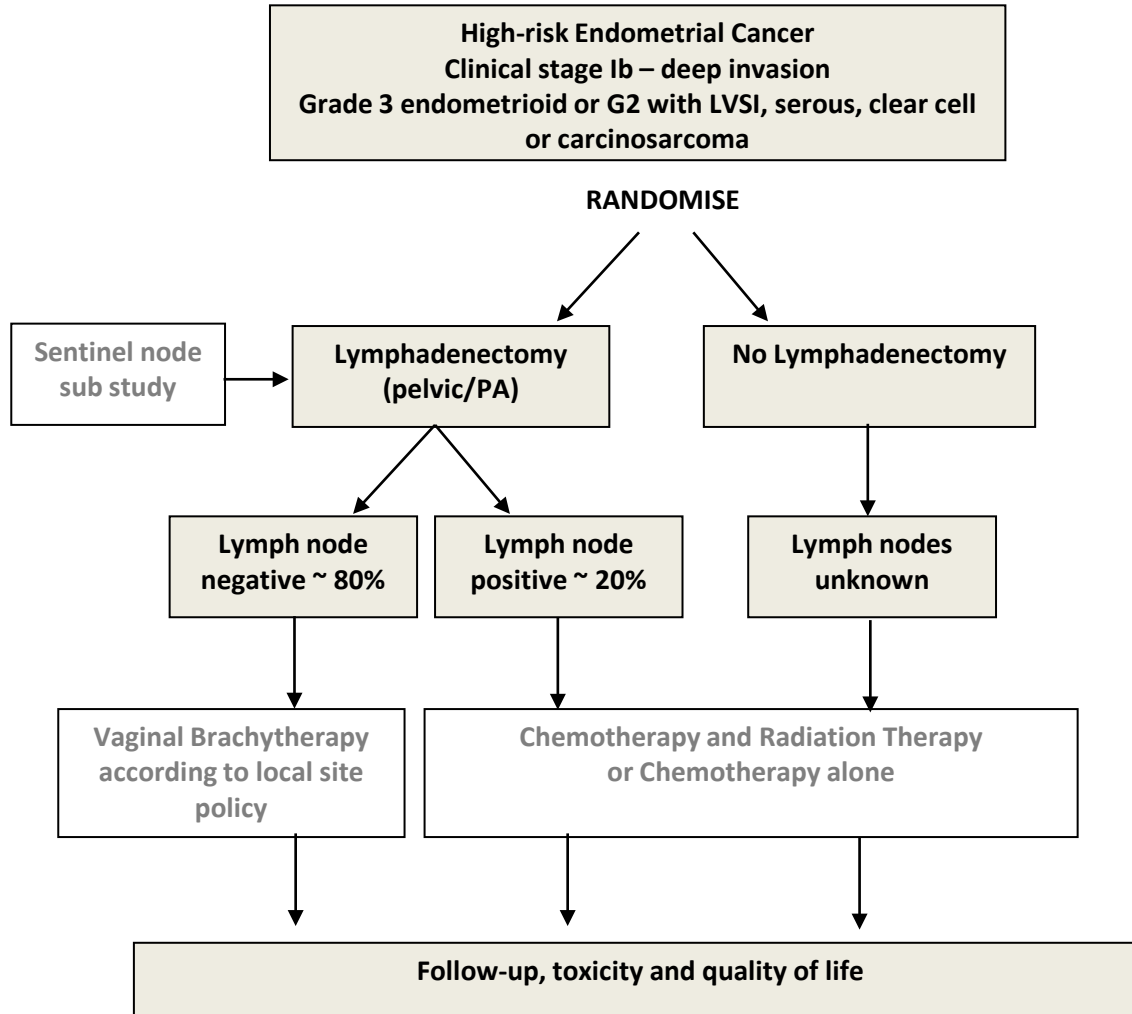


Objectives

- ▶ Determine OS of adjuvant therapy given to to all high-risk (unknown nodes) compared with only to node positive (staged nodes) women
- ▶ Secondary: compare toxicity, surgical complications, PFS, quality of life, cost effectiveness
- ▶ Sentinel node biopsy (with ultrastaging): evaluate accuracy compared with systematic dissection



STATEC Trial



Statistics

- ▶ Non-inferiority trial: exclude survival difference of 5%
- ▶ OS for no-LND arm 75%, non-inferiority defined as OS >70%: 2820 pts required
- ▶ This design would allow detection of superiority of 5% (more likely than 10%)

- ▶ Superiority trial with either of the arms providing 10% survival benefit: 1500 pts required (underpowered to determine non-inferiority)



GCIG commitment

- ▶ Four groups committed (NCRI, GOG US; ANZGOG; DGOG), five have expressed interest (KGOG; MITO; SGOG; GICOM; ICORG; NCIC)
- ▶ International trial management group to be appointed (2 reps from each group)



Timelines

- ▶ Protocol outline has be submitted to CRUK – August 2013
- ▶ TMG to write draft protocol – to follow after approval of outline (notice November/December)
- ▶ Full protocol submission to CRUK due March 2014
- ▶ Final decision on funding April 2014
- ▶ to update status re NCI

