STATEC

Selective Targeting of Adjuvant Therapy for Endometrial Cancer

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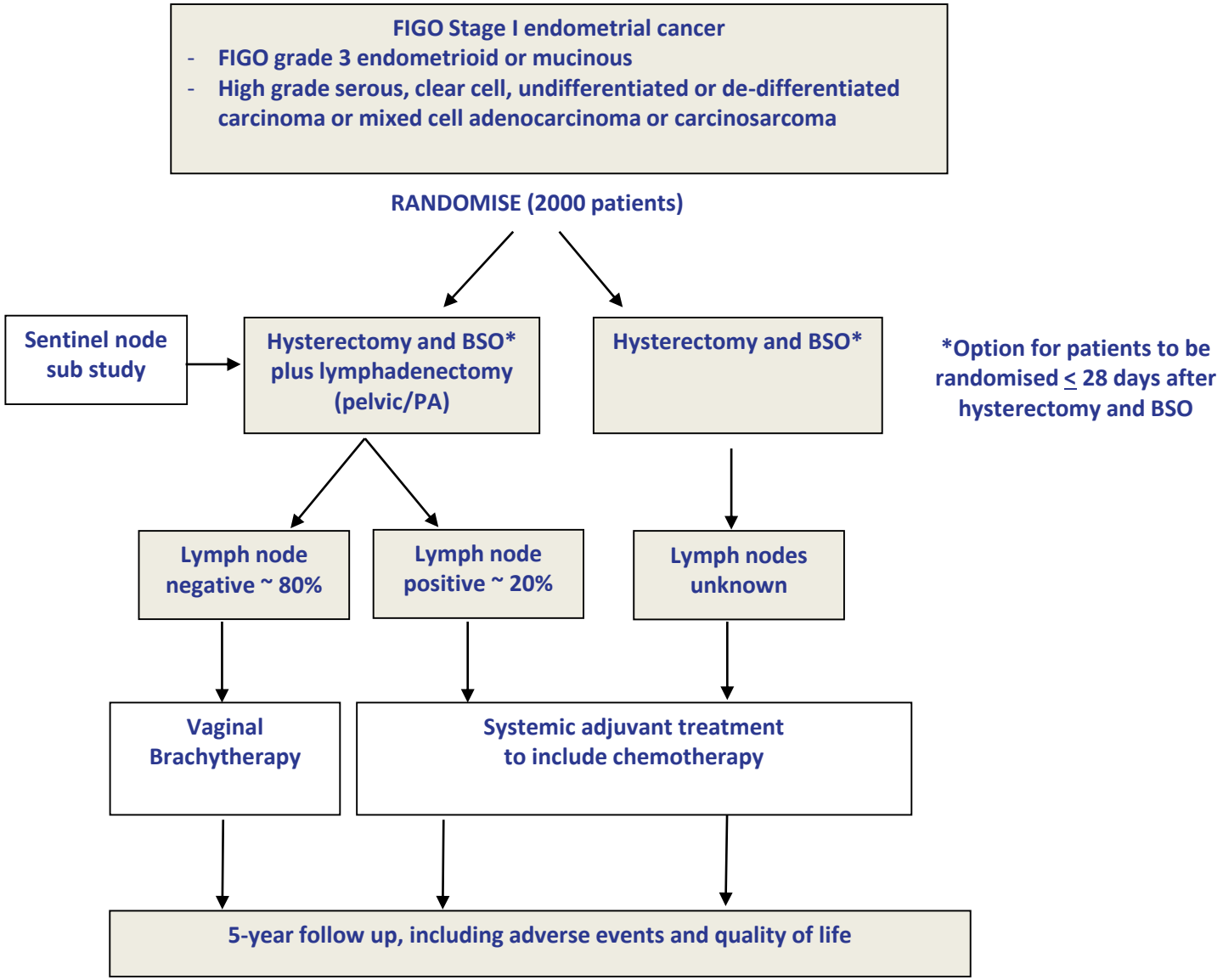
Hypotheses

- Lymphadenectomy is not independently therapeutic
- Improvement in survival may require systemic adjuvant treatment i.e. chemotherapy +/- radiotherapy
- Tailoring adjuvant treatment based on node status may limit adverse events with non-inferior survival
- Sentinel node biopsy may be as effective as full lymphadenectomy to triage patients to adjuvant treatment

Summary Eligibility

- Histologically confirmed high risk apparent FIGO stage I EC:
  - FIGO grade 3 endometrioid or mucinous
  - High grade serous, clear cell, undifferentiated or de-differentiated or mixed cell adenocarcinoma or carcinosarcoma
- Surgery to be performed ≤ 5 weeks after randomisation
- ECOG performance status 0-2
- Ability to undergo adjuvant chemotherapy +/- radiotherapy
- Adjuvant treatment to commence ≤ 8 weeks after surgery


FIGO Stage I endometrial cancer
- FIGO grade 3 endometrioid or mucinous
- High grade serous, clear cell, undifferentiated or de-differentiated carcinoma or mixed cell adenocarcinoma or carcinosarcoma
RANDOMISE (2000 patients)
Sentinel node sub study
Hysterectomy and BSO* plus lymphadenectomy (pelvic/PA)
Hysterectomy and BSO*
*Option for patients to be randomised ≤ 28 days after hysterectomy and BSO
Lymph node negative ~ 80%
Lymph node positive ~ 20%
Lymph nodes unknown
Vaginal Brachytherapy
Systemic adjuvant treatment to include chemotherapy
5-year follow up, including adverse events and quality of life

Current Status

- 3 confirmed GCIG groups - NCRI, ANZGOG, DGOG
- Interest from NSGO and KGOG
- Protocol finalised
- NCRI to submit for approvals end of June
- Aim to open to recruitment Q3 2016