STATEC

Selective **T**argeting of **A**djuvant **T**herapy for **E**ndometrial **C**ancer

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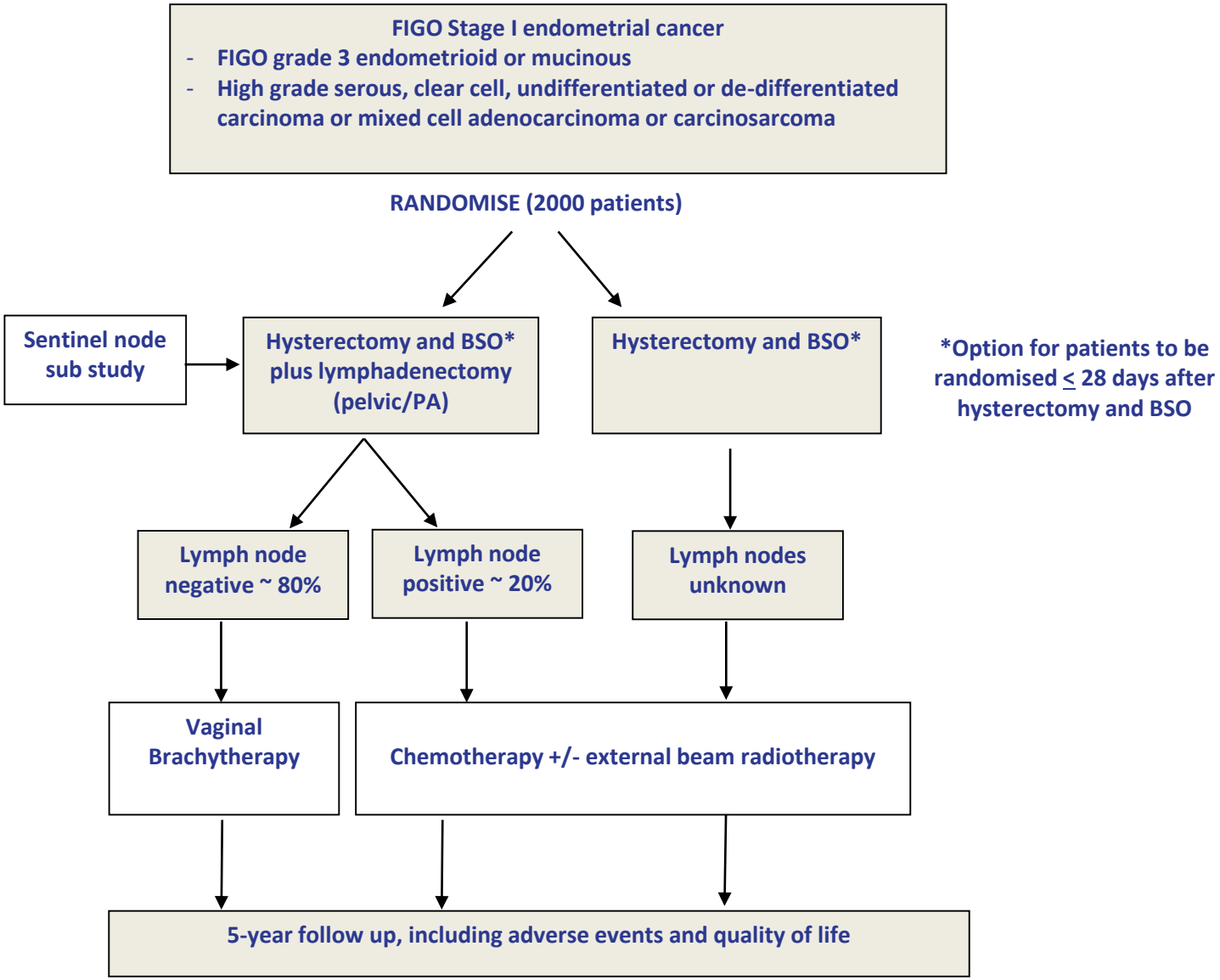
Development

- 2012 – Leiden GCIG Consensus Meeting
- Primary 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 I endometrial cancer.
- Single large randomised international trial
- Due to open October 2016. CRUK & UCL Cancer Trials Centre co-ordinating the trial – UK, Netherlands, Australia, and other countries


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
Chemotherapy +/- external beam radiotherapy
5-year follow up, including adverse events and quality of life

Outcomes

- **Primary endpoint is overall survival**
  - Disease-free, endometrial cancer-event free and endometrial cancer-specific survival
  - Pelvic and extra-pelvic relapse-free survival
  - Adverse events, QOL, cost effectiveness
  - Effectiveness of sentinel lymph node procedure to detect metastases

- Non-inferiority trial: exclude survival difference of 5%

  1990 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)

- Translational program – consent to tissue storage, central storage (Portec)

SLN sub-study (LND arm)

- Any Blue Dye
  - Patent Blue
  - Isosulphan
  - Methylene blue
- Or ICG
- +/- Tc99
- Cervical injection +/- fundal