



### FGOG Adjuvant UPSC/clear cell study

Coordinator : F. Amant

- Randomized Phase III trial.
- Patients will be randomized to receive either **adjuvant chemotherapy (paclitaxel/carboplatin 6 courses)** or **no chemotherapy**.
- The design will test for **superiority** of the chemotherapy arm over the no chemo arm.

## FGOG Adjuvant UPSC/clear cell study End-points

- Primary end-point: disease free survival after three years
- Secondary end-point: overall survival after three years

## FGOG Adjuvant UPSC/Clear cell study Inclusion criteria

- Histological proven **serous or clear cell** endometrial cancer (**mixed** endometrial carcinomas with serous or clear cell component, irrespective of percentage of serous or clear cells are allowed)
- **Adequate staging procedure** including hysterectomy, bilateral salpingo-oophorectomy, cytology, adequate pelvic lymphadenectomy, omentectomy, peritoneal biopsies
- FIGO surgical **stage I-IIa**

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### Exclusion criteria

- Endometrial cancer of the following subtype: uterine leiomyosarcoma, endometrial stromal sarcoma, carcinosarcoma, undifferentiated endometrial cancer, endometrioid endometrial cancer (any grade)
- Endometrial carcinoma with positive pelvic nodes (Stage IIIc) or evidence for transperitoneal spread (Stage IV).

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### Statistical analysis

- Primary endpoint: PFS rate at 3 years.
- Statistical test: Fisher exact test (2-sided)
- Parameters:
  - alpha error = 0.05
  - beta error = 0.20
- Expected rate in the control arm (no chemo) = 69% PFS at 3 yrs and in the experimental arm (chemo) = 95% PFS at 3 yrs
- Sample size: 2 x 38 patients = 76 patients in total.

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### Current status

- Approved by ethical committee in Leuven and **9 Flemish centers**.
- Financial support from Flemish Group Gynecological Oncology
- Accrual: **2/76**
- **Interest** from Scottish, AGO and Swiss groups
- Further through ENGOT.