# SENTICOL III Study

## International prospective validation trial of sentinel node biopsy in cervical cancer. (GINECO-CE106 / ENGOT-Cx24)

Trial setting: tumour type/stage: cervical cancer; stage Ia1 – IIa1

Study Design: randomized, sIngle blind phase III trial

Sponsor(s): Hospital Besançon for GINECO

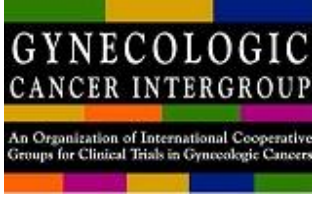
Planned No. of patients: 950

Current accrual: **11 registered and 5 randomized patients in France**

Other important information:

- Activation other countries + CCRN sites: Q4 2018/Q1 2019




- **Squamous or adenocarcinoma of the cervix,**
- Stage **Ia1** with lympho vascular emboli **to IIa1**,
- Maximum diameter **≤ 40mm**.

**Inclusion/exclusion criteria**

**ICF signature**

**Pre-study procedure**

*Pelvic examination, SLN mapping + biopsy, Frozen Section on SLN.*

Patients with bilateral detection without macroscopic suspicious node and negative frozen section on SLN **(pN0)**

Patients with nodal involvement **(pN1)**

**Randomisation**

**1 : 1**

950 patients

**Arm A (experimental) :**
SLN biopsy only
+ hysterectomy or trachelectomy

**Arm B (reference) :**
SLN biopsy
+ Pelvic Lymphadenectomy
+ hysterectomy or trachelectomy

**DFS, RFS, QOL, OS**

**Followed in a separate cohort to record treatment and outcomes**

# Interested groups and centres

- AGO
- NOGGO
- DGOG
- CTI
- G-GOC
- MANGO
- EORTC
- NCIC
- KGOG
- NSGO
- ANZGOG
- NCRI
- GOTIC
- MSKCC
- And CCRN sites….