

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

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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: 1 registered patient in France, 2<sup>nd</sup> of May, 2018

### Other important information:

-Activation other countries: Q3/Q4 2018

-Poster study in progress ASCO 2018

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

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

**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
- SAKK
- ICORG
- NCRI
- GOTIC
- MSKCC
- And CCRN sites....