

SENTICOL III Study

International prospective validation trial of sentinel node biopsy in cervical cancer

F Lecuru, M Leitao, P Mathevet, M Plante

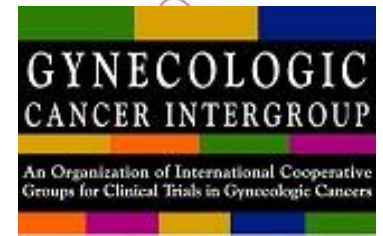
COORDINATING INVESTIGATOR	PR Fabrice LECURU
STUDY BIostatistician	Pr Franck BONNETAIN
QUALITY OF LIFE ANALYSIS	Dr Amélie ANOTA
TRIAL MANAGEMENT	Nathalie LE FUR
SPONSOR	University Hospital Besançon



Ongoing Trials – status update

SENTICOL III / GINECO

GINECO-CE106



Trial setting: **Cervical cancer; early stages (Ia1 LVSI+ - IIa1)**

Study Design: **Prospective randomized, single blind phase III trial**

Sponsor(s): **ARCAGY-GINECO, DRCI Besançon, INCa**

Planned No. of patients: **950** randomized

Current accrual: *Not started*

Other important information:

Funding OK for France and international coordination

Pending submission to authorities



State of the art



- ❑ Despite several studies and some prospective (randomized) trials, SLN biopsy is not a standard of care.
- ❑ SLN improves sensitivity, has a low FN rate (when quality criteria met), detects nodes outside of classical bassins and detects micrometastases (and ITC)
- ❑ Results of SENTICOL II
 - ❑ 105 SLN vs 101 SLN + PLN (in N0 patients)
 - ❑ Lymphatic complications 31.4 vs 51.5% (<0.001)
 - ❑ Neurological symptoms 7.8 vs 20.6% (p<001)



Our Goals

- ❑ To make SLN a new standard for treatment of early cervical cancer
 - ❑ Similar survival
 - ❑ Better QoL

- ❑ To provide benefits of SLN to all enrolled patients

Senticol III

Study Design



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

Inclusion/exclusion criteria
ICF signature

Pre-study procedure
Pelvic examination, SLN mapping + biopsy, Frozen Section on SLN.

Surgical & pathological quality assurance

950 patients

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



Quality assurance

❖ Centre selection

- Having participated to SENTICOL, SENTICOL II or other prospective study on SLN in cervical or endometrial cancer
- OR Treating at least 15 cases of early cervical cancer / year
- OR Trained for SLN + PLN of at least 15 cases of cervical or endometrial cancer
- AND Trained for the safety algorithm

- Use of isotope +/- blue dye (or ICG)
- Availability of pelvic/abdominal MRI, planar lymphoscintigraphy or SPECT, frozen section

- Pathologist trained for frozen section of SLN and ultrastaging of SLN
- Multidisciplinary board, radiation therapy, chemotherapy, clinical research facilities

❖ Centre assessment

- Random selection of reports

Present status



- Grant for the French part & international coordination
- Sponsor = CHU de Besançon
- Application to French authorities (May 2017)
- 50 sites in France
- ***1st inclusion in September***



Interested groups



- **AGO**
- **DGOG**
- **GOG**
- **ISGO**

- G-GOC
- NOGGOMITO
- MANGO
- EORTC
- NCIC
- KGOG
- ANZGOG
- SAKK
- ICORG
- And....





Thank you



- ❖ nlefur@arcagy.org
- ❖ fabrice.lecuru@aphp.fr
- ❖ franck.bonnetain@univ-fcomte.fr

