SENTICOL III Study
International prospective validation trial of sentinel node biopsy in cervical cancer

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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
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
**Sentricol III**

**Study Design**

- **Inclusion/exclusion criteria**
  - ICF signature
  - Pre-study procedure: Pelvic examination, SLN mapping + biopsy, Frozen Section on SLN.

**ICF signature**

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

**Pre-study procedure**

**950 patients**

- Patients with bilateral detection without macroscopic suspicious node and negative frozen section on SLN (pN0)
- Patients with nodal involvement (pN1)

**Randomisation**

- Arm A (experimental): SLN biopsy only + hysterectomy or trachelectomy
- Arm B (reference): SLN biopsy + Pelvic Lymphadenectomy + hysterectomy or trachelectomy

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

**Surgical & pathological quality assurance**

**DFS, RFS, QOL, OS**
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

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