

**EORTC 55994:**  
**Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO stage Ib2, IIa > 4 cm or IIb cervical cancer.**

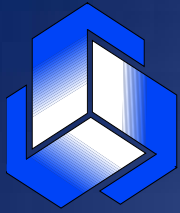
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# Cervix cancer. EORTC 55994.

## □ Main eligibility criteria:

- Cervical carcinoma of one the following histological types:
  - squamous cell carcinoma
  - adenosquamous cell or adenocarcinoma
- FIGO stage Ib2, IIa > 4 cm or IIb.
- WHO performance status 0-2.
- Age 18-75.
- No prior irradiation or chemotherapy.

# Cervix Cancer. Treatment Scheme

N=686

Eligibility Check

Randomization

*EORTC 55994*

## Arm 1: Neoadjuvant QT

Cisplatin based chemotherapy :

-min. cumulative cisplatin dose of 225 mg/m<sup>2</sup>

-25 mg/m<sup>2</sup> per week,

-final dose no later than D64

Followed by surgery (radical hysterectomy)

## Arm 2: concomitantly QT/RDT

Cumulative cisplatin dose 200-240 mg/m<sup>2</sup>.

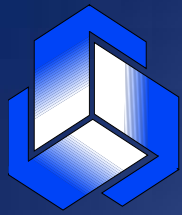
- Max 6 administrations.

- Dose 40 mg/m<sup>2</sup>, max 80 mg

External radiotherapy (45-50 Gy) in fractions of 1.8 Gy to 2 Gy + external boost or brachytherapy

- min. 75 Gy EQD2 to point A (80 Gy to High Risk PTV) is mandatory

- overall treatment time ≤ 50 days



# Endpoints. EORTC 5594

## Primary endpoint:

- Overall survival

## Secondary endpoints:

- Progression free survival
- Toxicity
- Quality of life



## EORTC 55994. Current status

- Activation of new sites ongoing
- Recruitment (November 8th 2013): 594 patients
- Given the **slow accrual** and the **very long-term follow-up needed** to accumulate the required number of events both for OS and PFS, the required number of events will not be reached within a reasonable timeframe.



## EORTC 55994. Current status

- The recommendation was then to redesign the trial with a **binary endpoint**.
- The first choice was OS rate at 5 years which was the initial objective of the trial.
- Under a 10% difference in OS rate at 5 years
  - ✓ OS rate at 5 years of 67% in the control arm
  - ✓ OS rate at 5 years of 77% in the experimental arm
  - ✓ Sample size required (two sided type I error of 5% and power of 80%): **625 patients**