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.

EORTC Study Coordinators:

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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.

PIs: G. Kenter, S. Greggi, F. Landoni

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^2
-25 mg/m^2 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^2.
- Max 6 administrations.
- Dose 40 mg/m^2, 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

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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