

EORTC 55994:

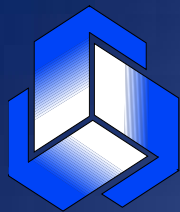
Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO stage Ib2, IIa > 4 cm or IIb cervical cancer.

EORTC Study Coordinators:

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Current portfolio of trials. 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/m²

-25 mg/m² per week,

-final dose no later than D64

Followed by surgery (radical hysterectomy)

Arm 2: concomitantly QT/RDT

Cumulative cisplatin dose 200-240 mg/m².

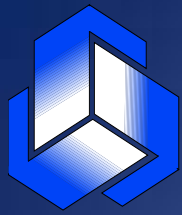
- Max 6 administrations.

- Dose 40 mg/m², 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



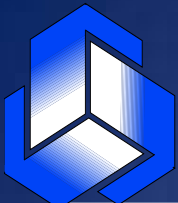
Endpoints. EORTC 5594

Primary endpoint:

- Overall survival

Secondary endpoints:

- Progression free survival
- Toxicity
- Quality of life



Activation of new sites

Country	Institutions	Status
Germany	Universitaetsklinikum - Essen	Insurance expected soon
Spain	Instituto Valenciano De Oncologia - Valencia	Contract- issues
France	Centre Regional Francois Baclesse - Caen Chr De Besancon - Hopital Jean Minjoz	Authority approval received. Ethics Committee Outcome expected soon.
Ireland	St. James'S Hospital - Dublin Cork University Hospital University College Hospital - Galway	ICORG: Group is still discussing their participation
Serbia	Institute of Oncology of Vojvodina; Institute of Oncology & Radiology - Belgrade	Membership application pending
United Kingdom	Belfast City Hospital - Belfast Guys & St Thomas Hospital - London	Activation of sites ongoing. Main issues: Material Transfer Agreement - Irradiation