

EORTC GCG 55994

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

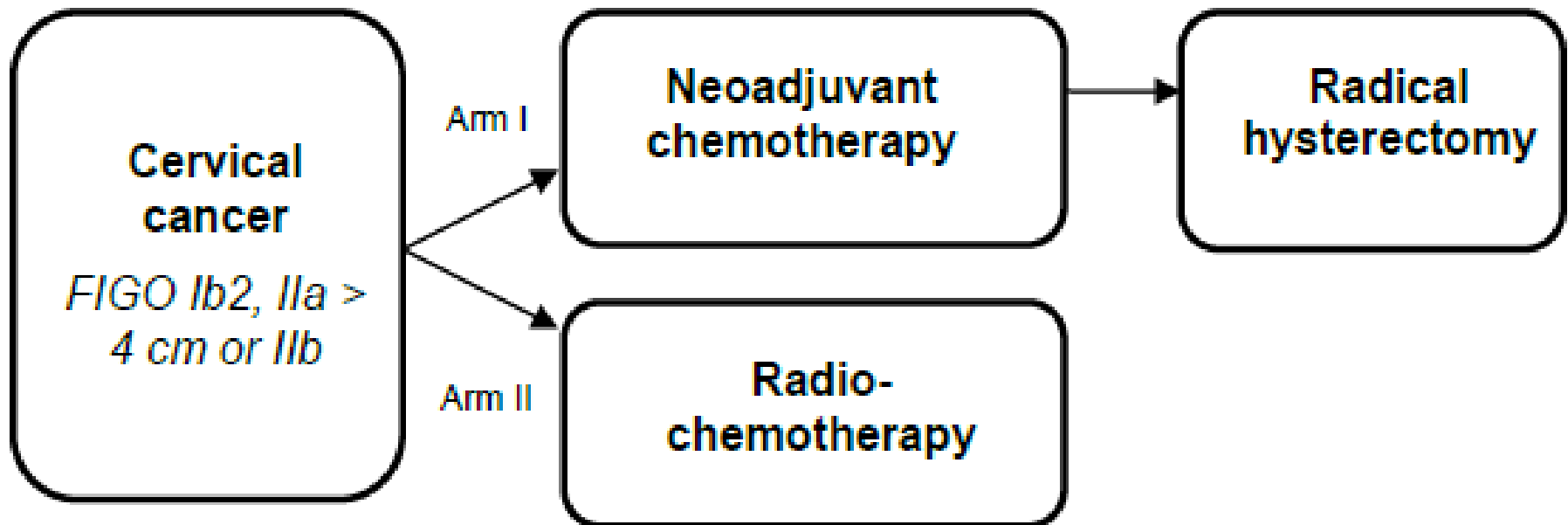
Trial setting:	FIGO stage Ib2, IIa > 4 cm or IIb cervical cancer
Study Design:	Randomized unblinded 2-arm randomized phase III
Sponsor(s):	EORTC GCG
Planned No. of patients:	626 pts (reached in June 2014)

Other important information:

- Primary end-point: OS at 5 years → study closure foreseen at June 2019.
- Data collection and cleaning ongoing.
- No interim analysis foreseen.
- Early publications on trial and treatment characteristics (not related to efficacy):
 - Short term toxicity (presented at IGCS 2016, updated for BGCS 2017)
 - Treatment characteristics (presented at IGCS 2016, updated for BGCS 2017)
 - Further planned abstracts under consideration.

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**SHORT TERM TOXICITY and PRELIMINARY RESULTS
FROM EORTC 55994 COMPARING
NEOADJUVANT CHEMOTHERAPY FOLLOWED BY SURGERY
TO CHEMORADIATION FOR
LOCALLY ADVANCED (Stage IB2-IIB) CERVICAL CANCER**

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EORTC Study Coordinators: G. Kenter, F. Landoni, S. Greggi

Lisbon, IGCS, nov 2016

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Conclusions from preliminary data

- This is the largest randomized trial in cervical cancer comparing NACT followed by radical hysterectomy with CCRT
- Short term safety is acceptable, mainly due to CT in both arms
- Discontinuation of protocol is high (**20-30%**)
- Pathological complete/ optimal response in NACT - arm = **37%**
- Complete response based on imaging in arm 2 = **49%**
- Adjuvant therapy in arm 1 for patients who underwent surgery = **27%**
- Survival data will follow **mid 2019**