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

EORTC Study Coordinators:

Dr. G. Kenter
Dr. F. Landoni
Dr. S. Greggi
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.
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

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