A PHASE III TRIAL OF POSTOPERATIVE CHEMOTHERAPY OR NO FURTHER TREATMENT FOR PATIENTS WITH NODE-NEGATIVE STAGE I-II INTERMEDIATE OR HIGH RISK ENDOMETRIAL CANCER. ENGOT-EN2-DGCCG / EORTC 55102

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Background: Patients with medium and high-risk stage I and II endometrial cancers have, despite radical surgery, high risk for local and distant progression. Adjuvant radiotherapy was unable to improve survival. Two phase III studies failed to show any difference in survival between radiotherapy and chemotherapy, though both studies had suboptimal chemotherapy regimens/included good prognosis patients. The GOG-122 phase III study in stage III & IV found significant improvement in survival in the chemotherapy arm. It is of utmost importance to clarify the role of adjuvant combination chemotherapy comparing to no further treatment in this patient population. Paclitaxel-Carboplatin combination chemotherapy is effective and well tolerated.

Methods: This multicenter, open-label, 1:1 randomized, phase 3 investigator-initiated study is evaluating postoperative chemotherapy compared with no further treatment in patients with medium- or high-risk, node negative stage I, or stage II endometrial cancer (stage 1: grade 3 endometrioid or any type 2 histology; stage 2: all patients). Patients have undergone hysterectomy and bilateral salpingo-oopherectomy and pelvic lymphadenectomy (minimum 12 pelvic nodes. Para-aortic LNE is optional). Adjuvant brachytherapy is permitted in both arms, though external beam radiotherapy is not allowed. Primary endpoint is overall survival, and secondary endpoints include disease specific survival, progression-free survival, rates of isolated pelvic, distant and mix relapses, quality of life, compliance and toxicity. Carboplatin (AUC5) and paclitaxel (175mg/m²) is given by iv every 3 weeks, total 6 courses. This trial will enrol 678 patients. This trial is enrolling patients. Interested institutions are welcome to join the study. NCT01244789.

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