CERVICE

PAROLA TRIAL

PARa-aOrtic LymphAdenectomy in locally advanced cervical cancer (PAROLA trial): a GINECO, ENGOT, and GCIG study

International multicenter, randomized, phase III study. Eligible patients will be randomized 1:1 between PET/CT staging followed by chemoradiation (control arm), or surgical staging followed by tailored chemo-radiation (experimental arm). Randomization will be stratified by tumor stage according to TNM classification, center, and adjuvant treatment

Background: positron emission tomography/computed tomography (PET/CT) fails to detect approximately 25% of aortic lymph node metastasis in patients with PET/CT stage IIIC1 cervical cancer. Surgical staging could lead to treatment modification and to improved para-aortic and distant control

Primary objectives: to demonstrate if chemoradiation with tailored external beam radiation field based on surgical staging and pathologic examination of the para-aortic lymph node is associated with improved 3-year disease-free survival compared with patients staged with PET/CT staging only

Major inclusion/exclusion criteria: main inclusion criteria are histologically proven PET/CT FIGO stage IIIC1 cervical cancer. Main exclusion criteria include unequivocal positive common iliac or para-aortic lymph node at pre-therapeutic imaging PET/CT

Primary endpoints: the primary endpoint is disease-free survival defined as the time from randomization until first relapse (local, regional, or distant), or death from any cause

The estimated date for completing accrual will be 2027