with MTIT (24.1% vs. 60.7%, P = 0.005). Wound breakdown was the most common complication in our cohort, which occurred less frequently in the M-MTIT group than in the MTIT group (10.3% vs. 35.7%, P = 0.022). Multivariate logistic regression analysis identified M-MTIT as an independent predictor of reduced risk of wound breakdown. The incidence of other complications, including lymphedema, wound infection and cellulitis was lower in M-MTIT group than in MTIT group; however, the differences did not reach statistical significance. Median follow-up time of this study was 33 months. The Kaplan-Meier survival graphs did not show significant differences in recurrence-free survival and overall survival between the two groups.

Conclusions M-MTIT correlates with lower morbidity rates and does not compromise oncological safety compared with MTIT. It could be considered as a safe and feasible option for vulvar cancer patients with locally advanced disease.

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323 ENGOT-EN9/LEAP-001: A PHASE 3 STUDY OF FIRST-LINE PEMBROLIZUMAB PLUS LENVATINIB COMPARED WITH CHEMOTHERAPY IN ADVANCED OR RECURRENT ENDOMETRIAL CANCER

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Background Prognosis and OS are poor in patients with advanced or recurrent endometrial cancer (EC). First-line standard of care for these patients is paclitaxel-carboplatin chemotherapy; however, more effective and tolerable therapies are needed. In the phase 1b/2 trial KEYNOTE-146, which assessed the PD-1 inhibitor pembrolizumab combined with the multikinase inhibitor lenvatinib, an ORR of 38% was observed in patients with previously treated advanced EC. ENGOT-en9-LEAP-001 (NCT03884101) is a randomized, open-label, active-controlled, phase 3 study investigating pembrolizumab + lenvatinib vs chemotherapy in patients with EC.

Trial design Patients with newly diagnosed advanced (stage III-IV) or recurrent EC not previously treated with antiangiogenic agents; systemic chemotherapy (unless within a chemoradiation regimen); PD-1, PD-L1, or PD-L2 inhibitors; or other T-cell receptor–targeted therapies will be eligible. Patients will be randomized 1:1 to receive pembrolizumab 200 mg Q3W + lenvatinib 20 mg daily or paclitaxel 175 mg/m2 Q3W + carboplatin AUC 6 Q3W. Randomization will be stratified by proficient vs deficient mismatch repair (pMMR vs dMMR) status. The pMMR population will be further stratified by prior chemoradiation (yes/no), measurable disease (yes/no), and ECOG performance status (0/1). Patients will receive treatment for ≤35 cycles of pembrolizumab vs 7 cycles of chemotherapy or until initiation of a new anticancer treatment, unacceptable AEs, or withdrawal of consent. Primary endpoints are PFS (per RECIST v1.1 by blinded independent central review) and OS. Secondary endpoints are ORR, health-related QOL, safety/tolerability, and lenvatinib pharmacokinetics. Exploratory endpoints are disease control rate, clinical benefit rate, and duration of response. Enrollment is ongoing.

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324 THE COMPLEXITY OF DECISION-MAKING FOR RISK-REDUCING SURGERY IN WOMEN WITH LYNCH SYNDROME

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Introduction Risk-reducing surgery (RRS) in Lynch Syndrome effectively prevents endometrial and ovarian cancers.