Objectives Determining para-aortic lymph node (PALN) status is the most important prognostic factor and a key point for the therapeutic strategy in locally advanced cervical cancer (LACC). When positive PALN is diagnosis, radiotherapy is extended to the para-aortic area. The radiation planning may be based on image staging while others recommend to rely on surgical. The gold standard to identify para-aortic extension is histological evaluation of PALN, but the survival benefit of surgical staging remains controversial. This study is a national, prospective, multicenter and non-randomized clinical trial evaluating the survival impact of surgical staging in patients with LACC.

Methods Eligible patients present with FIGO (2018) stage IB3, IIA2, IIB-IVA (excluded IIIC2r) and histologically confirmed cervical squamous cell carcinoma, adenocarcinoma, adeno-squamous cell carcinoma. According to patient’s willing, 1956 patients will be non-randomized to receive either CCRT (Pelvic EBRT/Extended-field EBRT + cisplatin (40 mg/m2) or carboplatin (AUC=2) every week for 5 cycles + brachytherapy) or Open minimally invasive PALN dissection followed by CT/MDCT/positron emission tomography and subsequent CCRT. The primary endpoint is PFS. Secondary endpoints are OS, surgical complications, imaging sensitivity and specificity. The sample size calculation of 1663 patients provides 90% power to detect a difference in survival at the two-sided 1% significance level using the log-rank test, considering a 15% reduction, a total of 1956 patients are required. This study began in June 2022 and will be accrued within 5 years. Enrollment is ongoing.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

References

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Objectives Cervical cancer is highly incident in Latin America (LATAM) and is frequently diagnosed in advanced stages. There is scarce information on clinical and epidemiological aspects of cervical cancer in LATAM. This study will provide data to develop comprehensive programs to improve cervical cancer prevention and treatment in the region.

Methods LACOG 0820 (EVITA LATAM) is an observational retrospective and prospective study that aims to characterize cervical cancer in LATAM. Patients from 16 research sites in 7 LATAM countries (Argentina, Brazil, Costa Rica, Dominican Republic, Mexico, Peru, Colombia), diagnosed with cervical cancer of any histology, FIGO 2018 stage IB2 or greater, since Jan 2018 or newly diagnosed during enrollment will be included. The factors to be evaluated comprise demographic and socio-economic (patient’s country, occupation, income, educational level, marital status, health insurance coverage) and clinical aspects (histology, stage at diagnosis, smoking history, hemoglobin level, renal function, time from diagnosis to initiation of definitive treatment for localized disease). Data will be collected from medical charts during 5 years from diagnosis. Tumor block will be collected from patients who agree at time of enrollment. A biorepository will be established to perform next generation sequence tests and describe tumor molecular characteristics. Based on prevalence of locally advanced cervical cancer in LATAM, 482 patients are expected to be enrolled in this study. As of 30 June 2022, 131 patients had been enrolled.

10.1136/ijgc-2022-igcs.517

Results Trial in progress: no available results at submission.

Conclusions Trial in progress: no available conclusions at submission.

References

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Abstracts

Paper 1: AFT-50 Endomap: A Phase I/II Multicohort Study of Targeted Agents with Atezolizumab (Atezo) for Patients (pts) with Recurrent or Persistent Endometrial Cancer (EC)


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Paper 2: A Phase I/II multicohort study of targeted agents with Atezolizumab (Atezo) for patients (pts) with recurrent or persistent endometrial cancer (EC)

Abstracts

Objectives The prognosis for women with recurrent or persistent EC after progressing on first-line chemotherapy is poor. The humanized monoclonal anti-programmed cell death ligand 1 (PD-L1) inhibitor, Atezo, has demonstrated monotherapy antitumor activity with an acceptable safety profile in recurrent EC. The AFT-50 EndoMAP trial is a platform trial designed to evaluate the efficacy and safety of Atezo in combination with biomarker-defined targeted agents in pts with recurrent or persistent EC.

Methods This is a phase IB/II non-randomized, multicenter, multicohort, biomarker-driven platform study for pts with recurrent/persistent EC having received no more than 2 prior lines of therapy. Based on genomic profile per FoundationOne® CDx (F1CDx) NGS assay, pts may be eligible for one of the following doublets: Atezo+ipatasertib (PI3K3CA/PTEN/ AKT1-altered cancers), Atezo+talazoparib (genomic loss of heterozygosity (LOH) ≥16%), Atezo+Trastuzumab emtansine (ERBB2/HER2 mutated and/or amplified tumors), Atezo+Tiragolumab (MSI-H and/or TMB>10 mut/MB), and Atezo+bevacizumab (biomarker unmatched). Pts will receive Atezo and the targeted agent until progression, unacceptable toxicity, withdrawal from the study, death, or study termination. The primary endpoint is confirmed overall response rate (ORR) for each biomarker. Secondary endpoints include 6-month PFS, disease control rate, duration of response, OS, and safety and tolerability. Additional arms may be added, as supported by evolving understanding of EC and molecular targets. EndoMAP is actively enrolling at 4 sites with a target of 25 sites in the US.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

Objectives Primary Objective: To evaluate the efficacy in terms of the probability of surviving progression free for at least 6 months (PFS at 6 mo). Secondary Objective: To determine the proportion responding by RECIST v1.1 in patients with advanced, persistent, or recurrent endometrioid endometrial cancer. To estimate the time to disease progression or death (PFS and OS endpoints). To describe the toxicities in patients receiving combination therapy with letrozole and abemaciclib with advanced/metastatic endometrial cancer.

Methods Key Eligibility Criteria:-Advanced (FIGO 2014 Stage III or IV), persistent, or recurrent endometrial carcinoma - Must have endometrioid histology (all grades allowed) (Hormone receptor status is not required for enrollment). -Must have measurable disease by RECIST v1.1. -Prior chemotherapy in the adjuvant setting for Stage I, II, or III is permitted. -Prior chemoradiotherapy for a pelvic recurrence is permitted. -Prior immunotherapy and/or targeted therapy is allowed in addition to, in combination with, in lieu of, or subsequent to prior chemotherapy. Regardless of circumstances, no more than one prior chemotherapy regimen (including chemoradiotherapy) is permitted, and no more than one additional systemic therapy is permitted. Hence, eligible patient may have received 0, 1, or 2 prior lines of systemic therapy and for women who received two prior lines of therapy, only one of them may have included chemoradiotherapy. -ECOG performance status of 0–1. -Must be able to swallow oral medications.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.