Introduction Sentinel-lymph node biopsy has safely replaced lymphadenectomy in the staging of many solid cancers. The aim of this study was to evaluate the sensitivity and specificity of sentinel-lymph-node mapping compared with the gold standard of complete lymphadenectomy in detecting metastatic disease for early stage ovarian cancer.

Methods In the SELLY multicentre, prospective, phase II trial (EUDRACT 2019-001088-58) patients with presumed stage I-II epithelial ovarian cancer and planned for immediate or delayed minimally-invasive comprehensive staging were eligible for study inclusion. Patients received an injection of indocyanine green and sentinel-lymph-node mapping followed by pelvic and para-aortic lymphadenectomy. Seven centers from in Italy participated in the trial. Negative sentinel lymph nodes (by haematoxylin and eosin staining on sections) were ultra-staged with immunohistochemistry for cytokeratin. The primary endpoint, sensitivity of the sentinel-lymph-node-based detection of metastatic disease, was defined as the proportion of patients with node-positive disease with successful sentinel-lymph-node mapping who had metastatic disease correctly identified in the sentinel lymph node.

Current Trial Status Between March 2018 and July 2022, 176 patients were enrolled but only 174 received complete study interventions. 100 (58%) patients had successful mapping of at least one sentinel lymph node and 15 of them (15.0%) had positive nodes. Of the latter, 11 of 15 (73.3%) patients had a correct identification of the disease in the SLN. In detail, 7 out of 11 patients required ultrastaging protocol. 4 patients with node-positive disease had a negative SLN. Enrollment was closed on January 2023. Data analysis is about to be completed.

AN PROSPECTIVE, SINGLE-ARM, PHASE II STUDY OF ALTERNATING REGIMENS OF FLUOZOPARIB AND ORAL ETOPOSIDE MAINTENANCE THERAPY, IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER: FARE TRIAL


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An alternative therapy option for advanced OC patients is debulking surgery; followed by platinum-based chemotherapy ± bevacizumab; followed by maintenance therapy with bevacizumab or monotherapy with PARP inhibitors. The expense of OC maintenance therapy might be substantial. However, the potential benefits of alternating regimens of PARP inhibitors and chemotherapy have not yet been explored. In the alternating regimens of fluzoparib and oral etoposide, both drugs function by directly targeting the DNA of tumour cells. Additionally, the adverse effects of each treatment may be controlled separately without any additive effects. The FARE trial aims to evaluate the efficacy and safety of alternating regimens maintenance therapy in Chinese patients with newly diagnosed advanced OC who are not at high risk of recurrence.

Methods The FARE trial is a single-center, investigator-initiated, single-arm, phase II trial of patients with FIGO stage III-IV high-grade serous or high-grade endometrioid OC. This study includes patients with tumors sample had to be available for central testing to determine BRCA mutation status and homologous-recombination deficiency (HRD) status, no visible residual tumor after primary cytoreductive surgery, and responses to the postoperative platinum-based combination chemotherapy. All enrolled patients are treated with this alternating regimen maintenance therapy for 24 months, until disease progression or unacceptable toxicity, or withdrawal of patient consent. Primary endpoint is progression-free survival (PFS).

Current Trial Status Trial in progress: there are no available results at the time of submission, and there are no available conclusions at the time of submission.
Introduction Despite the controversial role of radiotherapy (RT) in recurrent ovarian cancer (ROC), there might be a survival benefit irrespective of favorable clinical features according to a preliminary analysis. This prospective study was designed to compare the survival outcomes between standard care (SOC) with or without stereotactic ablative RT (SABR) to all recurrent sites in ROC.

Methods Patients with recurrent epithelial ovarian cancer with 10 or less metastatic sites at recurrence based on the number of SABR fields are eligible. Those who have a history of RT, single lesion sized >5 cm, or diffuse peritoneal carcinomatosis are not eligible. Patients will be stratified by factors as the followings; number of favorable factors (absence of ascites, platinum-sensitivity, CA-125, and ECOG performance), location of the lesion (lymph node vs. non-lymph node), and use of PARP inhibitor. Patients will be randomized (1:2) into SOC salvage treatment (arm 1) vs. SOC plus metastasis-directed SABR (arm 2). The primary endpoint is 3-year overall survival rate (58.5% for arm 1 and 74.4% for arm 2). A total of 270 patients will be required.

Current Trial Status A dummy-run study involving 4 representative clinical scenarios is under progress. To enhance compliance with the protocols, a three-tiered RT quality assurance (QA) process consisting of general credentialing, trial-specific credentialing with dummy run plus phantom QA, and individual case review has been performed. Currently, 32 patients from 16 sites are enrolled as of August 21st, 2023.

AS16. Screening/Early detection

Comparing Visual Inspection with Acetic Acid for Triage of HPV Self-Sample Positive Women in Ethiopia – A Randomised Controlled Trial

Introduction HPV vaginal self-sampling is more acceptable by women than health-provider cervical cancer screening methods. However, only a minority of HPV positive women will need treatment for pre-cancerous lesions, which requires an effective triage test. Visual inspection with acetic acid (VIA) is recommended as a triage, but the sensitivity and specificity are questioned. The aim of this randomised controlled study is to compare the accuracy of VIA with and without Lugol’s Iodine (VILI).

Methods All women from an urban Ethiopian cohort with a cervix are eligible. Participants each collect two vaginal self-samples for HPV DNA analysis at Addis Ababa University laboratory. HPV positive women are stratified according to age and pregnancy status, and then randomized to either VIA or VIA with VILI (RedCap software). They are then examined at a clinic according to the allocated triage test. All women, except those pregnant, have a biopsy taken from the lesion or at 12 and 6 o’clock. If a lesion is visualized, they are immediately treated, unless pregnant. All biopsies are evaluated by a senior pathologist.

Current Trial Status 940 participants have been screened with an HPV vaginal self-sample (Date 16/7/2023). 131 were hrHPV positive and have visited the VIA clinic. 175 HPV positive women are needed to be examined at the clinic to get enough statistical power for the analyses we hope to reach in September 2023. Final results will be presented at IGCS.