EPV277/#126 A CROSS-SECTIONAL, NON-INTERVENTIONAL, MULTICENTRIC STUDY TO DETERMINE THE PREVALENCE OF HOMOLOGOUS RECOMBINATION DEFICIENCY AMONG WOMEN WITH NEWLY DIAGNOSED, HIGH-GRADE, SEROUS OR ENDOMETRIOID OVARIAN CANCER

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Objectives Background Homologous recombination deficiency (HRD) is common in women with newly diagnosed high-grade serous ovarian and other morphologically related cancers. Exploiting the prevalence of HRD positive status can help optimize the use of targeted therapies in these patients and improve survival. Due to limited statistics, the study is aimed to determine global as well as country-specific (Egypt, Lebanon, Malaysia, Russia, Singapore, Taiwan, Saudi Arabia, Turkey, and United Arab Emirates) data on the prevalence of HRD positive patients using locally developed tests and commercial kits.

Methods Method Study design and population: This cross-sectional, non-interventional, multicentre observational study will enroll a minimum of 405 women (≥ 18 years) with high-grade serous or endometrioid ovarian, primary peritoneal, and/or fallopian tube cancer having histopathology report and formalin-fixed paraffin-embedded (FFPE) tumour tissue block (s). FFPE tissue blocks will be used for HRD status and BRCA mutation testing. Objective: Primary endpoints include prevalence of patients with positive HRD status. Secondary endpoints include 1) Region- and country-specific prevalence of the patients with a) positive HRD status, b) positive tBRCA1m/tBRCA2m; 2) risk factors associated with these patients. Exploratory endpoints include clinical characteristics of overall patient population and by geographical regions. Statistical analysis: Analyses will be performed using full analysis set (FAS). Logistic regression analysis will be used to identify the potential risk factors.

Results Trail in progress.

Conclusions Importance The study will generate reliable evidence on prevalence of HRD positive patients and help health care professionals to understand the clinical and genetic characteristic of the disease in various countries guiding optimal treatment.

EPV278/#248 A RANDOMIZED CONTROLLED PHASE II CLINICAL TRIAL OF APATINIB PLUS CHEMOTHERAPY IN THE FIRST-LINE(1L) TREATMENT OF IVB STAGE, RECURRENT OR PERSISTENT CERVICAL CANCER

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Objectives This study evaluates the efficacy and safety of apatinib combined with chemotherapy in cervical cancer.

Methods In this open-label phase II study, eligible patients were randomized(1:1) to receive treatment: Arm A) oral apatinib 375 mg once daily + intravenous paclitaxel (P) and cisplatin (DDP) or carboplatin (carb); Arm B) intravenous P and DDP or carb. Chemotherapy was administered for 4–6 cycles followed by apatinib. The primary endpoint was PFS assessed by RECIST1.1, and secondary endpoints included OS, ORR, DCR, DOR, and safety/tolerability.

Results 61 patients were randomized to Arm A (n = 31) and Arm B (n = 30). Until March 30, 2021, the median follow-up was 10.7 months (range 1.73–32.23). Compared with patients in Arm B, patients in Arm A showed a higher PFS (13.6 vs. 5.2 months, HR, 0.455; 95% CI 0.239–0.865; P = 0.014), ORR (58.10% vs. 23.3%), and DCR (80.60% vs. 53.3%). Treatment-related AEs (TRAEs) occurred in 87% (A) and 40% (B); Grade ≥3 TRAEs occurred in 77% (A) and 30% (B), respectively. The most commonly reported grade ≥3 AEs were hematologic in nature (eg, neutropenia) and consistent with known chemotherapy AEs. Serious TRAEs were reported in 8 patients (22.6% [A]; 3.3% [B]); TRAE leading to death was reported in 1 patient in Arm A.

Conclusions As 1L treatment of IVB stage, recurrent or persistent cervical cancer, the addition of apatinib to chemotherapy significantly improved PFS and showed a higher ORR and DCR than chemotherapy alone. No new safety issues were identified with the addition of apatinib to chemotherapy.

EPV279/#351 EPIK-O/ENGOT-OV61: A PHASE 3, RANDOMIZED STUDY OF ALPELISIB + OLAPARIB IN PATIENTS WITH NO GERMLINE BRCA MUTATION DETECTED, PLATINUM-RESISTANT OR -REFRACTORY, HIGH-GRADE SEROUS OVARIAN CANCER

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Objectives High-grade serous ovarian cancer (HGSOC) represents most epithelial ovarian cancers. Whilst initially responding to platinum-based therapy, ~75% of patients develop resistance, conferring poor prognosis. Homologous recombination repair proficiency is associated with platinum resistance and limited response to PARP inhibitors. PI3K pathway inhibition downregulates BRCA expression, abrogating homologous recombination repair proficiency, and may lead to (re)sensitization to PARP inhibitors. As alpelisib (PI3Kα inhibitor) + olaparib (PARP inhibitor) demonstrated preliminary synergism in platinum-resistant/refractory, BRCA-wild-type, recurrent HGSOC in a phase 1b study, the EPIK-O study is further evaluating this combination.

Methods EPIK-O/ENGOT-OV61 (NCT04729387) is a phase 3, randomized (1:1), open-label, active-controlled trial evaluating the efficacy and safety of alpelisib + olaparib versus single-agent chemotherapy in patients (N≈358) with no germline BRCA mutation, platinum-resistant/refractory HGSOC. Adult women with platinum-resistant/refractory, histologically confirmed HGSOC, high-grade endometrioid ovarian, fallopian tube, or primary peritoneal cancer, with no germline BRCA1/2 mutation, are included; patients must have received 1–3 prior systemic therapies. In Arm 1, patients receive alpelisib 200 mg orally OD + olaparib 200 mg orally BID; in Arm 2, patients receive paclitaxel 80 mg/m^2 IV weekly or pegylated liposomal doxorubicin 40–50 mg/m^2 IV Q28D (investigator's choice). The primary endpoint is progression-free survival per radiologic tumor assessment (RECIST 1.1) by a blinded independent review committee. Key secondary endpoint is overall survival. Other secondary endpoints include overall response rate, clinical benefit rate, safety, and quality of life.
Results Enrollment is planned in 28 countries; completion of data collection for the primary endpoint is anticipated in 2023.
Conclusions Not applicable.

EPV280/#317 A BIZZARE CASE OF ECTOPIC MOLAR PREGNANCY IN BROAD LIGAMENT PROGRESSING TO GTN

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Objectives Molar pregnancy occurring at an ectopic site is a rare phenomenon. Such cases are mostly found either in fallopian tubes, uterine cornua or in the ovaries. Only one case of broad ligament molar pregnancy has been reported in literature so far and ours being the first case of a broad ligament ectopic molar pregnancy progressing to GTN. This case report is being presented with the objective of raising the awareness of molar pregnancies occurring at ectopic sites and highlighting the importance of follow-up for such rare cases.
Methods A suspected case of ruptured right tubal ectopic pregnancy presented to emergency with suspiciously high beta HCG level of 85000 mIU/ml. Intraoperatively a distinct mass, separate from uterus and fallopian tube measuring around 8 cms was seen between the leaves of broad ligament. Right salpingo-ophorectomy with excision of broad ligament and right pelvic peritoneum was done. On final histopathology, a diagnosis of broad ligament ectopic complete molar gestation was made.
Results Because of high initial beta HCG levels, large size of ectopic molar mass and fear of losing the patient to follow-up, prophylactic chemotherapy with single agent methotrexate 50 mg alternating with folinic acid was started. After a brief fall, post surgery, beta HCG started rising for three consecutive weeks despite continued chemotherapy. Gradually with dose modification of methotrexate to 75 mg (6 cycles) she responded and continues to be in remission after seven months.
Conclusions This bizzare case clearly substantiates the existence of such rare conditions and also reinforces the importance of follow-up.

EPV281/#407 SINGLE-DOSE METHOTREXATE IN THE TREATMENT OF LOW-RISK GESTATIONAL TROPHOBLASTIC NEOPLASIA – AN UPDATED RESULTS

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Objectives Low-risk gestational trophoblastic neoplasia (GTN) with WHO prognostic score of 0 to 6 has high cure rate. The aim of the study was to evaluate the effectiveness of single-dose methotrexate infusion in women with low-risk GTN.
Methods In this single centre retrospective cohort study, 115 women with low-risk GTN were treated between January 2000 and October 2019 with an intravenous bolus of 100 mg/m^2 of methotrexate followed by a 12-hour infusion of 200 mg/m^2. Serum human chorionic gonadotropin (hCG) levels were monitored weekly. If the hCG level dropped by 10-fold after 2 weeks, no further chemotherapy was given. Otherwise, chemotherapy was continued 2-weekly until 3 cycles post-normalisation of hCG. Characteristics between the 2 groups with or without complete remission with this regimen were compared.
Results All 115 women with low-risk GTN were cured. The overall complete remission rate with methotrexate was 85.2%, with 60.9% of women requiring a single-dose of methotrexate alone, and 24.3% requiring continuation of chemotherapy with 2-weekly methotrexate. 14.8% of women had unsatisfactory response with methotrexate alone and were cured with combination of methotrexate and actinomycin-D. The pre-treatment hCG levels were significantly lower in women who were cured with single-dose methotrexate regimen compared to those who failed this regimen (median hCG 1227 versus 3335 IU/L; P = 0.037).
Conclusions Single-dose methotrexate regimen offers an effective option for women with low-risk GTN and a low pre-treatment hCG level.

EPV282/#442 CASE REPORT: CHORIOCARCINOMA PRESENTED AS A VAGINAL TUMOR

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Objectives Choriocarcinoma is a highly vascular tumor of the trophoblast with immense metastatic potential to the lung, liver, brain or vulva. Next to the lung, vulvo-vaginal metastasis comprises 30% of all metastatic incidences. Metastasis in this region is often misleading in its initial appearance. Here we present case of vaginal metastasis of choriocarcinoma which was misdiagnosed initially.