

**Exclusion Criteria**

- Pelvic Mass >8 cm
- open surgical approach considered necessary following MDT review.
- Women lacking capacity to the extent they are unable to understand or complete trial documentation/questionnaires will be excluded from the trial.

MIRRORS inclusion criteria are intentionally wide, not restricting by Body Mass Index (BMI), patient comorbidity or Ca125 values.

Surgery will commence with an initial laparoscopic assessment followed by a decision to proceed to robotic or open interval debulking surgery. The aim of surgery is to remove all visible disease safely by whichever route. If conversion to open surgery is required to complete this, then it will be done.

**Results** All women recruited to MIRRORS, whether eventually undergoing robotic or open surgery, will be followed up to assess recovery, complication rate, pain and quality of life.

If the following Success Criteria are met, we will progress to MIRRORS-RCT:

- ≥20% of women eligible for the study accept inclusion in MIRRORS.
- Robotic IDS Complication rate is not higher than for open interval debulking surgery

- Conversion to open surgery rate not greater than 50% in patient group deemed suitable for Robotic IDS following initial diagnostic laparoscopy.

**Conclusion** Robotic surgery is unlikely to be suitable in all cases of ovarian cancer, particularly those with large pelvic masses or extensive disease around the upper part of the abdomen, however, it has the potential to provide significant recovery and quality of life benefits. Ultimately we would like to determine whether, in selected women, robotic surgery offers improved quality of life and recovery with equivalent overall and progression free survival.

**Disclosures** Anil Tailor: Proctor for Intuitive Surgical

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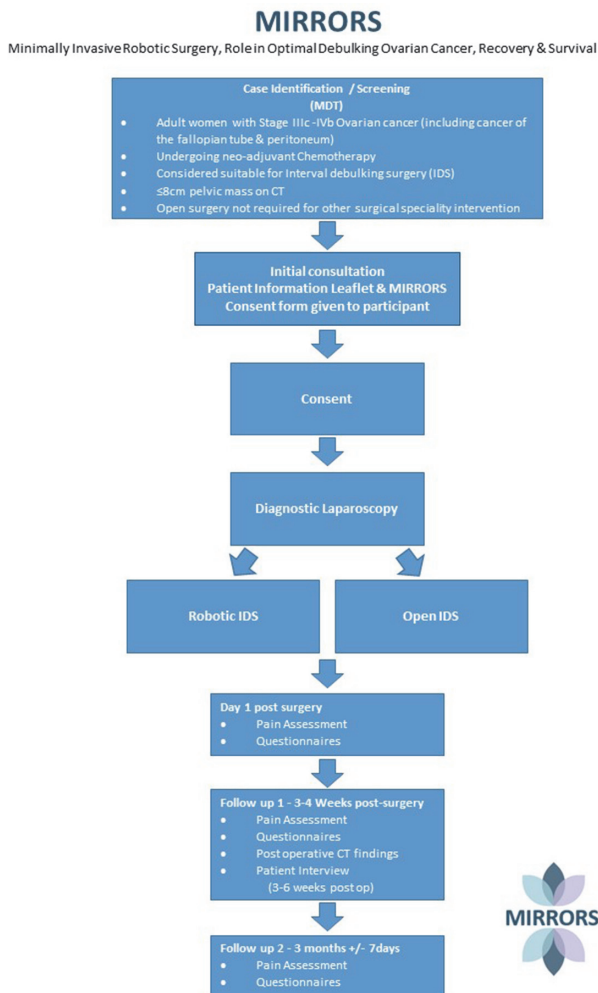
**387** **ENGOT-EN6/GOG-3031/NSGO-RUBY: A PHASE 3, RANDOMISED, DOUBLE-BLIND, MULTICENTER STUDY OF DOSTARLIMAB + CARBOPLATIN-PACLITAXEL VERSUS PLACEBO + CARBOPLATIN-PACLITAXEL IN RECURRENT OR PRIMARY ADVANCED ENDOMETRIAL CANCER (EC)**

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**Background** Carboplatin-paclitaxel is standard systemic anti-cancer therapy for recurrent or advanced EC for which surgery and/or radiation are not curative. Dostarlimab (TSR-042) is an anti-programmed cell death (PD)-1 humanised monoclonal antibody that has demonstrated antitumour activity and an acceptable safety profile in patients (pts) with recurrent or advanced EC in the GARNET trial. The RUBY trial will evaluate the efficacy and safety of dostarlimab in combination with carboplatin-paclitaxel in recurrent or primary advanced EC compared with carboplatin-paclitaxel alone.

**Trial Design** This is a global, randomised, double-blind, multi-center, placebo-controlled study. Eligible pts must have first recurrent or primary stage III or stage IV EC with a low potential for cure by radiation therapy or surgery alone or in combination. Pts with carcinosarcoma are eligible for enrolment. 470 pts will be enrolled from approximately 160 sites in the ENGOT countries, United States, and Canada. Stratification factors are DNA mismatch repair status (proficient [p], or deficient [d] MMR), prior external pelvic radiotherapy (yes or no), and disease status (recurrent, primary stage III or primary stage IV). Pts will be randomised 1:1 to receive combination dostarlimab 500 mg or placebo + carboplatin AUC 5 + paclitaxel 175 mg/m<sup>2</sup> every 3 weeks for 6 cycles followed by dostarlimab 1000 mg or placebo monotherapy every 6 weeks for up to 3 years in the absence of progressive disease, death, unacceptable toxicity, or patient/physician decision to



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withdraw from the study. The primary endpoint is progression-free survival (PFS) as assessed by the investigator in the all-comers population and the dMMR population per RECIST version 1.1. Secondary efficacy endpoints are PFS assessed by blinded independent central review per RECIST version 1.1, overall survival, objective response rate, duration of response, disease control rate, safety and tolerability, and patient-reported outcomes.

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Drs. Hanker and Valabrega have nothing to disclose.

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#### PHASE 3 TRIAL OF TUMOR TREATING FIELDS CONCOMITANT WITH WEEKLY PACLITAXEL FOR PLATINUM-RESISTANT OVARIAN CANCER: ENGOT-OV50/GOG-329/INNOVATE-3

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**Introduction/Background** Tumor Treating Fields (TTFields) are a non-invasive, antimitotic cancer therapy. The Phase 2 INNOVATE study demonstrated safety of TTFields/weekly paclitaxel in 31 PROC (platinum-resistant ovarian cancer) patients (Vergote Gyn Onc 2018); efficacy: median PFS 8.9 months, 25% partial response, 71% clinical benefit and 61% 1-year survival rate. This phase 3 ENGOT-ov50/GOG-329/INNOVATE-3 study [NCT03940196] investigates TTFields plus weekly paclitaxel in PROC patients.

**Methodology** Patients (N=540) will have PROC (RECIST V1.1) within 6 months of last platinum therapy with maximum of 2–5 prior lines of systemic therapy, ECOG 0–1 and no peripheral neuropathy >grade1. Patients with primary refractory disease will be excluded. Patients will be randomized 1:1 to weekly paclitaxel alone or weekly paclitaxel (starting of dose 80 mg/m<sup>2</sup> weekly for 8 weeks, and then on Days 1, 8, and 15 for subsequent 28-day cycle ) plus TTFields (200 kHz for 18 hours/day and continued if no progression in the abdominal or pelvic regions ('in-field region') per RECIST V1.1. Clinical follow-up will be performed q4w, with radiological follow-up (CT or MRI scans of the abdomen and chest) q8w. The primary endpoint is overall survival. Secondary endpoints: PFS, objective response rate, AEs, and quality of life (EORTC QLQ-C30 with QLQ-OV28). Sample size (n=540) will detect an increase in median OS from 12 to 16 months (HR 0.75). Data Monitoring Committee (DMC) meeting (March 2020) concluded that data to-date showed no safety issues and recommended trial continuation.

**Results** TiP N/A

**Conclusion** TiP N/A

**Disclosures**

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#### BIOPSAR STUDY: ULTRASOUND-GUIDED PREOPERATIVE BIOPSY TO ASSESS HISTOLOGY OF SARCOMA-SUSPICIOUS UTERINE TUMORS. A NEW STUDY PROTOCOL

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Topic: Trials in progress abstract

**Introduction/Background** The preoperative differential diagnosis between a uterine fibroma and a sarcoma is a challenge. Available diagnostic tools are rather inconclusive to distinguish between two pathologies. However, potential accurate diagnostic methods would be of great clinical impact in order to optimize surgical treatment.

**Methodology** A prospective multi-center interventional study will be performed. Ten tertiary French centers will participate in the present study. The overall inclusion study period will be 2 years, overall study duration will be 5 years. Patients greater than 35 years old, diagnosed with suspicious uterine tumor and needing surgical intervention will be included. Uterine tumors will be considered as suspicious in case of rapid tumor growth ( $\geq 30\%$  of the maximum diameter in 1-year interval), symptomatic tumors in postmenopausal women, tumors characterized by certain suspicious ultrasound criteria history of treatment with tamoxifen and genetical predisposal to cancer syndromes. Included patients will undergo preoperatively a Vaginal Ultrasound-Guided Biopsy (VUGB). There will be two histopathological diagnoses for each patient, the first based on the biopsy specimen received preoperatively (Index test) and the second based on the surgical specimen of uterus resected 'en block'. These diagnoses will be compared in order to assess diagnostic performance of VUGB. Histological criteria used for both diagnoses will be that of Bell et al which were revised by OMS 2014 classification.