Disclosures This trial is supported by Eli Lilly and Company which supplies the study drug abemaciclib and Kom Op Tegen Kanker (Stand Up Against Cancer) which provides a grant.

#140 SURVEILLANCE OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 WITH DUAL P16/KI-67 IMMUNOCYTOCHEMISTRY STAINING. TRIAL PROTOCOL AND PRELIMINARY REPORT

Kimon Chatzistamatiou*, Vasilios Theodoulidis, Dimitrios Zouzoulas, Panagiotis Tzitzis, Anastasia Sarieva, Iliana Sofianou, Eleni Mpili, Themistoklis Mikos, Grigorios Grimbizis, Dimitrios Tsolakidis. *Aristotle University of Thessaloniki, Thessaloniki, Greece*

10.1136/ijgc-2023-ESGO.870

Introduction/Background Cervical intraepithelial neoplasia (CIN) grade 2 is considered a high-grade squamous intraepithelial lesion requiring surgical treatment. Excisional cervical procedures, though, have been linked to an increased risk of preterm birth in subsequent pregnancies. Therefore, and given the fact that the vast majority of CIN2 cases will regress, there is a tendency to avoid surgical treatment for women who wish fertility preservation. The aim of the CIN2DIN study is to determine the diagnostic accuracy of P16/Ki-67 immunocytochemistry (ICC) for the timely detection of CIN3 +, among women with untreated CIN2, compared to cytology.

Methodology According to the study design, women with biopsy confirmed CIN2, after written informed consent, will be subjected to cervicovaginal sampling for p16/Ki-67 ICC (CINtec PLUS, Roche laboratories AG, Mannheim, Germany), cytology and high-risk Human Papillomavirus (hrHPV) testing (cobas® HPV Test, Roche Molecular Systems, Pleasanton, CA, USA) (t=0). After six months (t=1), participants will be subjected to colposcopy, and, cervicovaginal sampling for cytology and p16/Ki-67 ICC. After 12 months (t=2) participants will be subjected to colposcopy, and, to cervicovaginal sampling for hrHPV testing, cytology and p16/Ki-67 ICC. Participants will be also examined after 18 and 24 months (t=3, t=4, respectively). Examinations at t=3 and t=4 will be similar to t=1, and t=2 respectively. All women after visit t=4 exit the study and are referred to treatment according to the local guidelines.

Results To date 5 women with biopsy proven CIN2 have been recruited. Those women have been subjected to pap test, hrHPV testing, and p16/Ki-67 ICC.

Conclusion The CIN2DIN study is original and innovative. So far, no studies have been conducted on the value of P16/Ki-67 ICC for CIN2 surveillance. If the study identifies high correlation of P16/Ki-67 ICC to colposcopy, larger studies could be designed to investigate longer-term reassurance for the surveillance of women with untreated CIN2 without colposcopy.

Disclosures The authors have nothing to disclose

#145 INTERNATIONAL VARIATIONS IN POST-OPERATIVE MORBIDITY AND MORTALITY FOLLOWING GYNAECOLOGICAL ONCOLOGY SURGERY (GO SOAR1)

[1,2]Faiza Gaba*, [3]Karen Ash, [4]Oleg Blyuss, [5]Nicolò Bizzarri, [6]Paul Kamfwa, [7]Allison Saiz, [2]Shantini Paranjothy, [8]David Cibula. *[1]The Royal London Hospital, London, UK; [2]University of Aberdeen, Aberdeen, UK; [3]Aberdeen Royal Infirmary, Aberdeen, UK; [4]Queen Mary University Of London, London, UK; [5]Fondazione Policlinico Universitario A. Gemelli, IRCCS, UOC Ginecologia Oncologica, Dipartimento per la salute della Donna e del Bambino e della Salute Pubblica, Rome, Italy; [6]Cancer Diseases Hospital, Lusaka, Zambia; [7]Northwestern University, Chicago, USA; [8]Charles University and General University Hospital, Prague, Czech Republic*

10.1136/ijgc-2023-ESGO.871

Introduction/Background Gynaecological malignancies affect women in low and middle income countries (LMICs) at disproportionately higher rates compared with high income countries (HICs), but little is known about global variations in access, quality and outcomes in gynaecological cancer care. The aim if our study was to evaluate international variation in post-operative morbidity and mortality following gynaecological oncology surgery between LMIC and HIC settings.

Methodology Multicentre, international prospective cohort-study of women undergoing surgery for primary ovary/uterus/cervix/vulva/vagina/gestational trophoblastic malignancies (NCT04579861). Multilevel logistic-regression determined relationships within three-level nested models of patients within hospitals/countries.

Results We enrolled 1820 patients from 73 hospitals in 27 countries (1078 (59.2%) high income countries, 453 (24.9%) upper middle income countries, 174 (9.6%) lower middle income countries, 115 (6.3%) low income countries). Mean follow-up was 58.7 and 55.7 days from date of surgery in LMICs/HICs respectively. Overall-morbidity (Clavien-Dindo I-IV) for all tumour-groups was 34.7% (233/672) and 33.5% (338/1009), whilst mortality 2.1% (14/672) versus 1% (10/1009) for LMICs/HICs respectively. Minor-morbidity (Clavien-Dindo I-II) for all tumour-groups was 26.5% (178/672) and 26.5% (267/1009), whilst major-morbidity (Clavien-Dindo III-V) 8.2% (55/672) and 7% (71/1009) for LMICs/HICs respectively. Higher minor-morbidity was associated with previous laparoscopic surgery (OR=1.435, 95%CI=1.046–1.966, p=0.025), COVID-19 positive status (OR=5.025, 95% CI=1.262–20.008, p=0.022), pre-operative mechanical bowel preparation (OR=1.474, 95%CI=1.054–2.061, p=0.023), longer surgeries (OR=1.253, 95%CI=1.066–1.472, p=0.006), greater blood loss (OR=1.274, 95%CI=1.081–1.502, p=0.004), and occurrence of intra-operative complication (OR=2.203, 95%CI=1.498–3.241, p<0.001). Minimal-access-surgery was protective against minor-morbidity (OR=0.522, 95%CI=0.371–0.735, p≤0.001). Higher major-morbidity was associated with longer surgeries (OR=1.37, 95%CI=1.128–1.664, p=0.002), greater blood loss (OR=1.398, 95% CI=1.175–1.664, p≤0.001), and seniority of lead-surgeon with junior surgeons three times more likely to have a major-

complication (OR=2.982, 95%CI=1.509–5.894, p=0.002). 50% versus 25% of all surgeries were performed by junior surgeons in LMICs/HICs respectively.

Conclusion LMICs were associated with greater post-operative major-morbidity. Capacity to rescue patients from surgical complications is a tangible opportunity for meaningful intervention.

Disclosures None.

#172 STREAM-I/AGO-OP.11/ENGOT-EN22: EVALUATION OF PREOPERATIVE CLINICAL AND TRANSLATIONAL SELECTION CRITERIA FOR CYTOREDUCTIVE SURGERY IN ENDOMETRIAL CANCER – STEP 1 OF THE STREAM (SURGICAL TREATMENT IN ADVANCED AND RECURRENT ENDOMETRIAL CANCER MANAGEMENT) INITIATIVE

[1]Fabian Trillsch*, [2]Lorenzo Ceppi, [3]Pierre-Emmanuel Colombo, [4]Alexander Reuß, [5]Dana Josephy, [6]Joanna Kacperczyk-Bartnik, [7]Zoia Razumova, [8]Aleksandra Strojna, [9]Oleksandr Zub, [10]Jalid Sehouli, [11]Christian Marth, [1]Sven Mahner, [12]Philipp Harter, [13]Christoph Grimm, [10]Alexandra Wagner. *[1]AGO and Department of Obstetrics and Gynecology, LMU University Hospital, LMU Munich LMU University Hospital, LMU Munich, Munich, Germany; [2]MaNGO and Gynecology and Obstetrics Department, Grande Ospedale Metropolitano Niguarda, Milano, Italy; [3]GINECO and Department of Surgical Oncology, Montpellier Cancer Institute (ICM), Montpellier, France; [4]AGO and Coordinating Center for Clinical Trials of the Philipps-University of Marburg, Marburg, Germany; [5]ISGO and Gynecology-Oncology Unit, Sheba Medical Center, Tel-Aviv, Israel; [6]PGOG and Departament of Obstetrics and Gynecology, Medical University of Warsaw, Warsaw, Poland; [7]NSGO-CTU and Department of Women's and Children's Health, Karolinska University Hospital, Stockholm, Sweden; [8]CEEGOG and Department of Gynecology and Gynecologic Oncology, Evangelische Kliniken Essen Mitte, Essen, Germany; [9]CEEGOG and Clinical oncology and gynecology department, Chernihiv medical center of modern oncology, Chernihiv, Ukraine; [10]NOGGO and Department of Gynecology with Center for Oncological Surgery, Charité Gynecologcial Cancer Center and European Competence Center for Ovarian Cancer, Berlin, Germany; [11]AGO-Austria and Department of Obstetrics and Gynaecology, Innsbruck Medical University, Innsbruck, Austria; [12]AGO and Department of Gynecology and Gynecologic Oncology, Evangelische Kliniken Essen-Mitte, Essen, Germany; [13]AGO-Austria and Division of General Gynecology and Gynecological Oncology, Gynecologic Cancer Unit, Medical University Vienna, Vienna, Austria*

10.1136/ijgc-2023-ESGO.872

Introduction/Background Endometrial cancer (EC) is the most common gynecological cancer in Europe with approximately 20% of patients being diagnosed in advanced stage (FIGO III-IV). Until now, only few studies exist for cytoreductive surgery (CRS) in advanced stage reporting of complete cytoreduction in 18–75% cases. Evidence for EC from large multicenter analyses data is missing and the indication for CRS is widely based on individual and/or institutional decision algorithms.

Methodology STREAM-I/AGO-OP.

11/ENGOT-en22 is a retrospective, non-interventional, multicenter study aiming to identify preoperative clinical and molecular selection criteria for CRS. Patients who underwent CRS for advanced or recurrent EC at participating centers between 01/2011 and 12/2020 will be included. Available tumor material from CRS will be collected for evaluation of molecular classification and translational research. A multiple logistic regression identifying predictive factors for complete resection at CRS will be established using a stepwise covariate selection in the full clinical dataset. Therefore, a sample size of 800 patients was calculated based on estimated complete resection rates and number of independent variables.

Results As a result of this analysis, STREAM-II is planned as a consecutive prospective, single-arm, non-interventional, multicenter trial validating the predictive score established within the present study. Following confirmation, STREAM-III is planned to be a randomized, multicenter phase III trial evaluating CRS in EC.

Conclusion STREAM-I represents the first step towards Level I evidence for CRS in EC by identifying patients who most likely benefit from a radical surgical approach. STREAM-I will provide information to develop consecutive trials prospectively evaluating the impact of CRS in EC (STREAM-II/-III).

Disclosures No direct conflict of interest for this surgical trial exists. Further relation to companies have been disclosed and uploaded.

#205 ROSELLA (GOG-3073, ENGOT-OV72/MITO): A PHASE 3 STUDY OF RELACORILANT + NAB-PACLITAXEL VS. NAB-PACLITAXEL IN ADVANCED, PLATINUM-RESISTANT OVARIAN CANCER

[1]Domenica Lorusso*, [2]Andrea Bagameri, [3]Erin Bishop, [4]Anita Chudecka-Glaz, [5]Alix Devaux, [6]Laurence Gladieff, [7]Mary E Gordinier, [8]Jae-Weon Kim, [9]Jacob Korach, [10]Michael E Mccollum, [11]Linda Mileshkin, [12]Bradley J Monk, [13]Shibani Nicum, [14]Angélica Nogueira-Rodrigues, [15]Ana Oaknin, [16]David O'Malley, [17]Mauro Orlando, [18]Lyndah Dreiling, [19]Iulia Cristina Tudor, [20]Alexander B Olawaiye. *[1]Fondazione Policlinico Universitario A. Gemelli IRCCS and Catholic University of Sacred Heart, Rome, Italy; [2]National Institute of Oncology, Budapest, Hungary; [3]Medical College of Wisconsin, Milwaukee, USA; [4]Department of Gynecological Surgery and Gynecological Oncology of Adults and Adolescents, Pomeranian Medical University, Szczecin, Poland; [5]Oncology department of Grand Hopital de Charleroi, Chaleroi, Belgium; [6]Institut Claudius Regaud, IUCT Oncopole, Toulouse, France; [7]Norton Cancer Institute, Louisville, USA; [8]Department of Obstetrics and Gynecology, Seoul National University, Seoul, South Korea; [9]Sheba Medical Center, Tel Aviv University, Tel Aviv, Israel; [10]Virginia Oncology Associates, Norfolk, USA; [11]Department of Medical Oncology, Peter MacCullum Cancer Centre, Melbourne, Australia; [12]University of Arizona College of Medicine, Creighton University School of Medicine, HonorHealth Research Institute, GOG-Foundation, GOG-Partners, Scottsdale, USA; [13]University College London Cancer Institute, London, UK; [14]Federal University of Minas Gerais, Dom Oncologia and Oncoclinicas – Brazil, Belo Horizonte, Brazil; [15]Vall d'Hebron Institute of Oncology (VHIO), Hospital Universitari Vall d'Hebron, Barcelona, Spain; [16]The Ohio State University and the James Cancer Center, GOG, Columbus, USA; [17]Instituto Alexander Fleming, Buenos Aires, Argentina; [18]Corcept Therapeutics, Inc, Menlo Park, USA; [19]Corcept Therapeutics, Inc., Menlo Park, USA; [20]University of Pittsburgh, Pittsburgh, USA*

10.1136/ijgc-2023-ESGO.873

Introduction/Background Single agent chemotherapies are commonly used in platinum-resistant ovarian cancer, but outcomes are generally poor. Cortisol, which acts by binding to the glucocorticoid receptor (GR), can suppress apoptotic pathways used by cytotoxic agents. The GR is abundantly expressed in ovarian tumours and high GR expression is associated with poor outcomes. Data indicate that the selective GR modulator relacorilant can reverse cortisol's anti-apoptotic effects, thereby enhancing chemotherapy efficacy. In a phase 2 study in patients with recurrent, platinum-refractory or platinum-resistant ovarian cancer, intermittently dosed relacorilant + nab-paclitaxel showed clinically meaningful improvement in progression-free survival (PFS), duration of response (DoR), and a trend toward improved overall survival (OS) without increased side effect burden compared to nab-paclitaxel monotherapy. This phase 3 study aims to confirm the findings of the phase 2 study in a larger patient population.

Methodology ROSELLA (GOG-3073, ENGOT-Ov72/MITO, NCT05257408) is a randomised, phase 3, 2-arm, open-label study of relacorilant + nab-paclitaxel vs nab-paclitaxel