IGCS 2025 CAPE TOWN

Annual Global Meeting, November 5–7, 2025

# IGCS 2025 Abstracts:
# Pragmatic Trial Concept Presentations

Pragmatic trial concept abstract presentations are included in the sessions listed below. Sessions with oral presentations will be recorded for on-demand viewing via the IGCS 360 Educational Portal as indicated. Featured printed posters (Poster Rounds) will be presented during morning and afternoon coffee breaks, and E-Posters will be available for on-demand viewing to registered attendees via the IGCS 2025 mobile application, IGCS 360 Educational Portal, and the onsite E-Poster stations.

**ORAL PRESENTATIONS:**

**Plenary: Pragmatic Trial Concepts**
Thursday, November 6, 09:30 - 10:00 | Hall A&B | in-person & on-demand

**FEATURED POSTER PRESENTATIONS:**

**Poster Rounds 2: Advances in Gynecologic Oncology Care**
Wednesday, November 5, 10:40 - 11:10 | Poster Area | in-person only

**Poster Rounds 14: Surgical Innovations & Outcomes**
Friday, November 7, 10:45 - 11:25 | Poster Area | in-person only

**E-POSTERS:**

No designated presentation slot – available for on-demand viewing to registered attendees.

**OP012 / #766**

**Topic:** *AS05. Social Responsibility: Global Health, Economic Challenges & Inequity*

# PROPOSAL FOR INTEGRATION OF SYNTHETIC AI GENERATED CONTROL ARM FOR CERVICAL CANCER CLINICAL TRIALS USING REAL WORLD DATA

**PLENARY: PRAGMATIC TRIAL CONCEPTS**

**Presentation:** *Oral Abstract Presentation*

Noelle Cloven[1], Leslie Randall[2], Sarper Toker[3], Michael Bookman[4]
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**Introduction:** The treatment landscape for patients with recurrent metatatic cervical cancer (rmCC) is rapidly evolving and the development and approval of new drugs has led to substantial improvements in patient outcomes. However, the traditional trial designs using standard-of-care (SOC) control arms pose ethical and logistical challenges, especially in low-resource settings. AI-generated synthetic control arms (SCAs) leveraging real-world data (RWD) allow all patients to receive investigational therapy, potentially improving recruitment, retention, and relevance of results.

**Objectives:** To develop and validate an AI-generated SCA for patients with recurrent metastatic cervical cancer (rmCC) following chemotherapy and immunotherapy.

**Trial Design:** Clinical data will be sourced from Flatiron Health and Genospace. Key variables include age, race, insurance status, histology, PD-L1 status, measurable disease, and prior treatments. Generative Adversarial Networks (GANs) may be used to simulate “digital twins” that match treated patients. The resulting datasets will be compared to control arms in current rmCC trials to assess clinical fidelity and methodological validity. We will focus on this validation process as proof of concept that could potentially expand the application of this technique.

**Feasibility and Implementation:** Anticipated challenges include data completeness, abstraction of unstructured trial-specific variables, and regulatory acceptance. Cohort timeframes and factors that drive treatment decisions will impact validity. Success will require collaboration among investigators, regulatory agencies, patient advocacy groups, industry, and biotech partners to support the integration of AI and RWD into trial design.

**Conclusion:** While barriers exist, AI-generated SCAs have the potential to ethically and efficiently transform clinical research in cervical cancer by reducing costs, accelerating timelines, and improving patient trial experiences.

**OP013 / #1101**

**Topic:** *AS06. Tumor Types / AS06d. Ovarian Cancer*

# VARIATION IN PRESCRIBING PRACTICES FOR STANDARD-OF-CARE (SOC) PARP INHIBITOR DOSING IN OVARIAN CANCER IN INDIA: A PILOT PHYSICIAN SURVEY USING R2CT STRATEGY IN IPIROC STUDY

**PLENARY: PRAGMATIC TRIAL CONCEPTS**

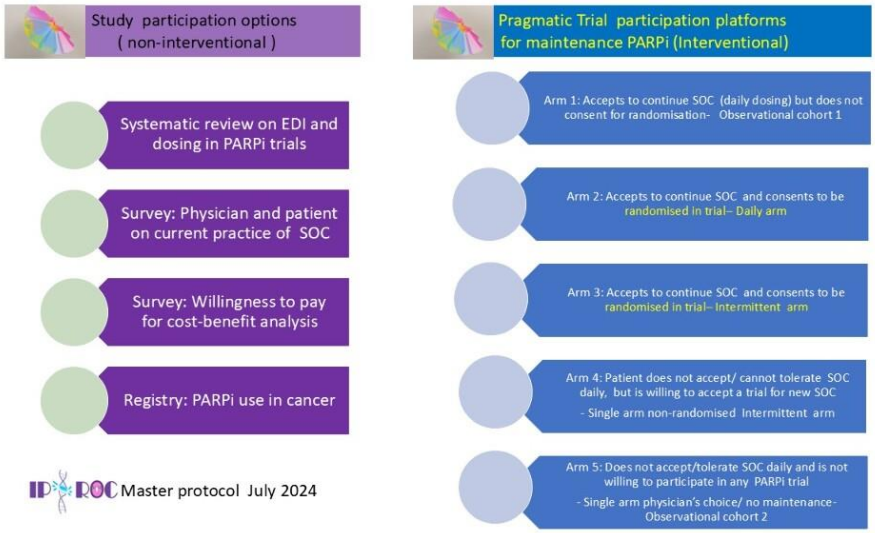
**Presentation:** *Oral Abstract Presentation*

Asima Mukhopadhyay[1], Daity Bhattacharjee[2], Kelley Kidwell[3], Sarita Kumari[2,4], Sofia Villar[5], Atanu Bhattacharjee[2], Bhramar Mukherjee[6]
[1]Kolkata Gynecological Oncology Trials and Translational Research Group, Kolkata, India, [2]Kolkata Gynecological Oncology Trials and Translational Research Group, Statistics, Kolkata, India, [3]University of Michigan, Biostatistics, Ann Arbor, United States of America, [4]Kolkata Gynecological Oncology Trials and Translational Research Group, Gyn Oncology, Kolkata, India, [5]University of Cambridge, Mrc Biostatistics, Cambridge, United Kingdom, [6]Yale School of Public Health, New Haven, United States of America

**Introduction:** There is limited representation of women from LMICs in PARP inhibitor (PARPi) trials translating into clinical practices based on maximal-tolerated-dosing and FDA approval. In addition to affordability/financial toxicity, hematological toxicities in Indian women with low-BMI or pre-existing anemia, cause frequent dose-reduction/discontinuations and varied non-standardized dose reduction practices amongst physicians, posing challenges in deciding the SOC arm in dose-optimization clinical trials.

**Objectives:** -Survey to determine SOC control arm dose for PARPi clinical trial

**Trial Design:**



A novel R2CT (Rationalizing and Reducing the cost of Running Randomised-Controlled-Trials in resource-restricted settings) strategy was developed for the IPIROC master protocol- a Rucaparib (PARPi) dose de-escalation study. A multi-faceted approach using systematic reviews, Physician and patient surveys were planned in parallel to developing the interventional trial arms (Figure1). The physician survey questionnaire (37 item) was developed following CROSS guidelines (EQUATOR Network), using REDCap database after several workshops/validation sessions. A pilot phase was intended to assess questionnaire feasibility in capturing accuracy and response amongst physicians on PARPi prescribing practices/experience/preference related to patterns/dose/DLT and preferred PARPi regimen for designing SOC control arm in clinical trials in India.

**Feasibility and Implementation:**

Table 1: Pilot survey data on Physician experience, practice and preferences for prescribing PARPi for ovarian cancer in India (N=33)

| **Hypothesis:** | **Significant proportion of Physicians do not practice starting PARPi at FDA recommended doses in the Indian Subcontinent and prefer a lower dosage as the physician's choice of SOC control arm for designing Phase 3 trials** | | |
|---|---|---|---|
| **Question** | **Answer (response rates)** | **Question** | **Answer (response rates)** |
| **Physician experience** | | | |
| Working in Govt set up | 23/32 (72%) | | |
| What % BRCA mutated eligible patients received PARPi for OC frontline maintenance in the last 12 months in your practice | 50% (Median) | | |
| What % HRD eligible patients received PARPi for OC frontline maintenance in the last 12 months in your practice | 10% (Median) | | |
| **Prescription practice** | **Rucaparib** | **Prescription practice** | **Olaparib** |
| What is your preferred dose of starting Rucaparib in clinical practice over last 12 months | | What is your preferred dose of starting Olaparib in clinical practice over last 12 months | |
| 1200 mg/day (FDA recommended dose) | 9/19 physicians (47%) | 600 mg/day (FDA recommended dose) | 13/22 physicians (59 %) |
| 600 mg/day or less | 9/19 physicians (47%) | 300 mg/day or less | 8/22 physicians (36 %) |
| How often did you start with FDA recommended dose of 1200/day of Rucaparib in the last 12 months | < 25% of time (11/20 physicians)<br>> 75% of time (5/20 physicians) | How often did you start with FDA recommended dose of 600/day of Olaparib in the last 12 months | < 25% of time (8/20 physicians)<br>> 75% of time (8/20 physicians) |
| Most commonly prescribed Rucaparib dose (mode) | 600 mg/day (8/17 physicians) | Most commonly prescribed Olaparib dose (mode) | 300 mg/day (8/20 physicians) |
| **Physician experience** | | **Physician experience** | |
| What is proportion of patients who could tolerate the FDA recommended dose of Rucaparib 1200mg/day | < 25% (9/16 physicians)<br>> 75% (0/16 physicians) | What is proportion of patients who could tolerate the FDA recommended dose of Olaparib 600 mg/day | < 25% (7/19 physicians)<br>> 75% (1/19 physicians) |
| Duration for which patients can tolerate Rucaparib 1200mg/day | < 3 months (13/17 physicians) | Duration for which patients can tolerate Olaparib 600 mg/day | < 3 months (12/18 physicians) |
| What % of patients can afford Rucaparib1200mg/day | < 25% (12/16 physicians) | What % of patients can afford Olaparib 600 mg/day | < 25% (10/19 physicians) |
| Commonest Dose limiting toxicity with Rucaparib | Haematological (11/17 physician) | Commonest Dose limiting toxicity with Olaparib | Haematological (15/20 physician) |
| **Physician experience** | | | |
| Preferred SOC daily dose of Rucaparib for control arm for designing a phase 3 clinical trial in India | 1200mg/day (2/16 physicians)<br>600 mg/day (7/16 physicians) | Preferred SOC daily dose of Olaparib for control arm for designing a phase 3 clinical trial in India | 600 mg/day (7/18 physicians)<br>300 mg/day (2/17 physicians) |
| Preferred PARPi for Physician's choice control arm for designing a phase 3 clinical trial in India | Olaparib (15/18 physicians) | Preferred PARPi dose for Physician's choice control arm for designing a phase 3 clinical trial in India | 600 mg/day (8/18 physicians) |

33 responses were analysed for the pilot phase (Table 1). >47% physicians rarely/never prescribed the FDA-recommended dose of Rucaparib (1200 mg/day); 600mg/day being the commonest prescribed starting dose and preferred dose for trials. <25% Indian women would tolerate FDA-recommended PARPi doses for > 3 months.

**Conclusion:** A provider advocacy approach is planned to improve response rates for the subsequent Phase 2 survey, in-depth interviews and focus group.prior to designing the Phase 3 pragmatic study

**OP014 / #296**

**Topic:** *AS06. Tumor Types / AS06d. Ovarian Cancer*

# REPURPOSE: PHASE II STUDY ASSESSING THE EFFICACY OF EFAVIRENZ, AN APPROVED HIV DRUG REPURPOSED AS AN ANTI-CANCER AGENT, IN PATIENTS WITH PLATINUM RESISTANT OVARIAN CANCER

**PLENARY: PRAGMATIC TRIAL CONCEPTS**

**Presentation:** *Oral Abstract Presentation*

Janine Lombard[1,2], Alison Davis[3], Hiren Mandaliya[2], Tarek Meniawy[4], Gaik Quah[2], Giovana Cellimarchett[5], Karen Briscoe[6], Rachel Campbell[7], Philip Beale[1], Brian Kelly[8], Mathias Bressel[9], Lisa Beatty[10], Georgia Ritchie[11], Leanna Pugliese[2], Kathryn Alsop[1], Caroline Ford[12], Deborah Marsh[13], Megan Jeon[14], Jana Stojanova[15], Gill Stannard[16], Nikola Bowden[17]
[1]ANZGOG, Sydney, Australia, [2]Calvary Mater Newcastle, Medical Oncology, Newcastle, Australia, [3]Canberra Regional Cancer Centre, Medical Oncology, Canberra, Australia, [4]Sir Charles Gairdner Hospital and University of Western Australia, Medical Oncology, Perth, Australia, [5]Manning Base Hospital, Medical Oncology, Taree, Australia, [6]MNCCI Coffs Harbour, Medical Oncology, Coffs Harbour, Australia, [7]Psycho-Oncology Co-operative Group, University Of Sydney, Sydney, Australia, [8]University of Newcastle, Newcastle, Australia, [9]Peter MacCallum Cancer Centre, Biostatistics, Melbourne, Australia, [10]Flinders University, Clinical Psychology, Adelaide, Australia, [11]MNCCI Port Macquarie, Medical Oncology, Po, Australia, [12]University of New South Wales, Translational Research Or Gynaecological Cancer Research, Sydney, Australia, [13]University of Technology Sydney, School Of Life Sciences, Sy, Australia, [14]University of Sydney, Psycho-oncology Co-operative Group, Sydney, Australia, [15]St. Vincent's Hospital Sydney, Department Of Clinical Pharmacology & Toxicology, Sydney, Australia, [16]City Natural Therapies, Camperdown, Australia, [17]University of Newcastle, Medicine And Public Health, Newcastle, Australia

**Introduction:** High-grade serous ovarian cancer (HGSOC) is the most common ovarian cancer subtype with a high risk of recurrence and poor prognosis. **Repurposing drugs** in this setting offers attractive cost and safety efficiencies. Compounds predicted to have PARP binding activity were identified and the top drug with cytotoxic potential and low toxicity was efavirenz. REPURPOSE will investigate the efficacy and safety of daily oral efavirenz for HGSOC that is heavily pretreated and potentially platinum sensitive or platinum resistant. REPURPOSE is a novel way of repurposing efavirenz to stabilise the disease burden and re-establish disease control.

**Objectives:** Primary objective: Efficacy of efavirenz in platinum resistant or heavily pretreated HGSOC by clinical benefit rate (Complete Response, Partial Response, or

Stable Disease) determined by RECIST v1.1 and/or CA125 GCIG criteria at 18 weeks. Secondary objectives: Frequency and severity of adverse events (CTCAE v5); Overall response rate; Duration of response; Progression Free Survival, Quantify plasma $C_{max}$ of efavirenz and Patient Reported Outcome Measures

**Trial Design:** A single-arm phase II study assessing the efficacy of oral efavirenz 600mg daily in platinum resistant and heavily pretreated HGSOC. 52 participants will be recruited over 3 years.

**Feasibility and Implementation:** REPURPOSE utilises a unique drug repurposing model designed to recruit from regional and rural Australian cancer centres. Participants at these sites are traditionally excluded from early phase studies (an issue in real world settings).

**Conclusion:** If Efavirenz demonstrates efficacy it will potentially become an affordable oral option for recurrent HGSOC, especially in lower resource settings.

**OP015 / #292**

**Topic:** *AS03. Patient-Centered Care / AS03c. Patient Advocacy & Survivorship*

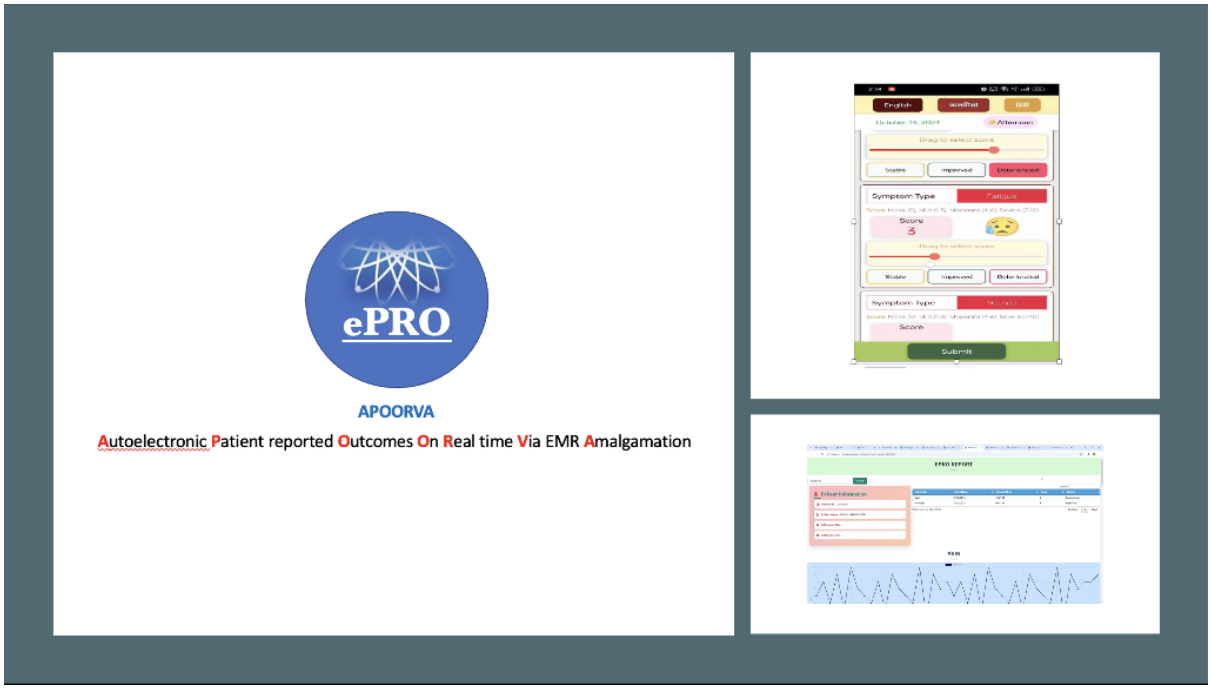
# FEASIBILITY STUDY OF EPRO USING ”APOORVA SMARTPHONE APP” FOR MONITORING DISTRESS AND HEALTH CARE NEEDS OF PATIENTS WITH UNPLANNED ADMISSIONS IN GYNECOLOGIC ONCOLOGY : A STEP TOWARDS IMPLEMENTING DIGITAL ONCO-CARE

**PLENARY: PRAGMATIC TRIAL CONCEPTS**

**Presentation:** *Oral Abstract Presentation*

Apoorva Tak[1], Debabrata Barmon[2]
[1]Bhagwan Mahaveer Cancer Hospital and Research Centre, Gynaecologic Oncology, Jaipur, India, [2]Dr B Borooah Cancer Institute, Gynaecologic Oncology, Guwahati, India

**Introduction: Background and rationale:** Since ESMO recommendations on implementing ePRO based management in cancer care were established in 2022, none of the studies so far have looked into its uptake in gynecologic malignancies . Incorporating ePRO’s in electronic medical records of patients allows capturing real world data on disease burden and quality of life of patients **Aim** To evaluate the feasibility of implementing ePRO monitoring intervention for patients with gynecological malignancies undergoing unplanned admissions with the ultimate goal of integrating ePRO into hospital EMR.

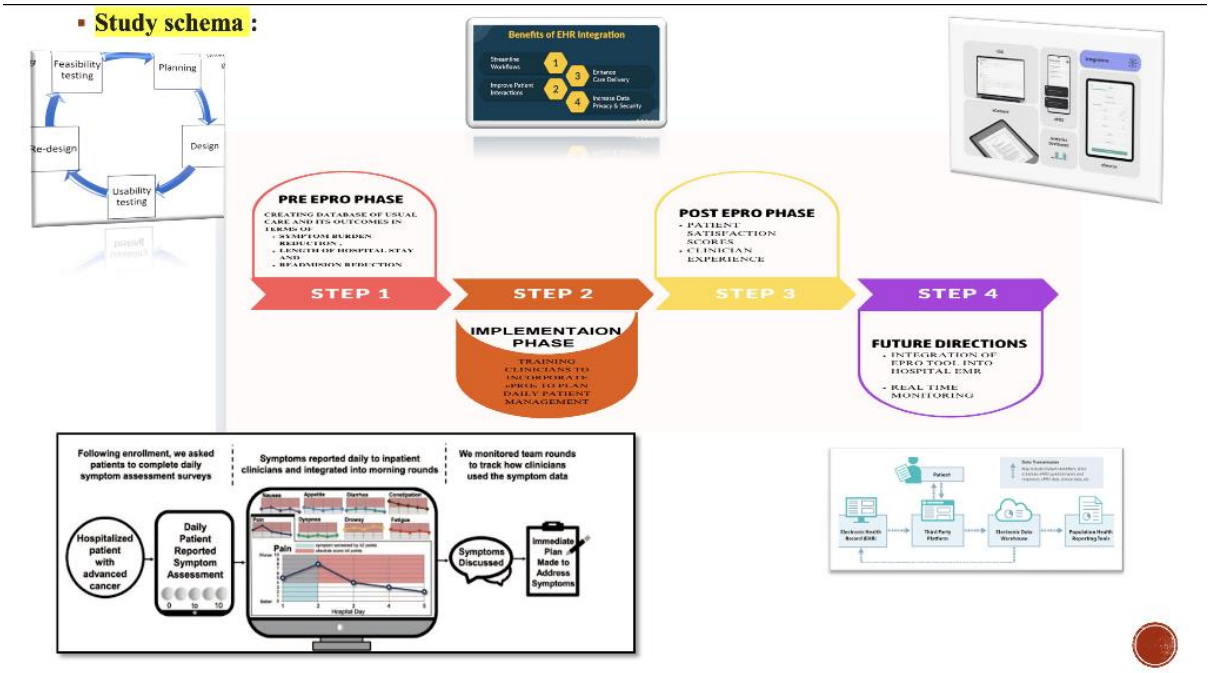


| QUESTIONAIRE FOR ePRO OF EMERGENCY GYNAECOLOGIC ADMISSIONS ( modified ESAS tool ) | | | |
|---|---|---|---|
| | | | |
| SYMPTOMS | DAY OF ADMISSION | SCORE NONE (0), MILD (1-3), MODERATE (4-6), AND SEVERE (7-10) | SYMPTOM BURDEN (IMPROVED / DETERIORATED) |
| Pain | | | |
| Fatigue | | | |
| Nausea and vomiting | | | |
| Drowsiness | | | |
| Appetite | | | |
| Dyspnoea | | | |
| Well being | | | |
| Seizures | | | |
| Not passed flatus and stool | | | |
| Abdominal distention | | | |
| Fever | | | |
| Headache | | | |
| Blood in sputum | | | |
| Maggot in perineum | | | |
| Shortness of breath | | | |
| Altered sensorium | | | |
| Urine leak from vagina | | | |
| Lower limb swelling | | | |

**Objectives: Primary** 1. To-assess-feasibility-of-implementing-an-ePRO tool-for-screening-and-determining-prevalence-of-distress-and-supportive-care-needs-among patients-with-gynecological-cancer-undergoing-unplanned-admissions-with-ultimate-goal-of-integration-with-EMR. **Secondary :** 2. To-evaluate-effect-on-patient-reported-symptom-burden. 3. To-assess-effect-of-health-care-utilization, in-terms-of-hospital-length-of-stay-and-30-day-readmission-rates-with-implementation-of-ePRO. 4. To-explore-patient-experience 5. To-explore-clinician's-experience 6. To-analyze-barriers-and-enablers-of-ePRO-implementation.

**Trial Design:** Single-arm-feasibility-study Mixed-method-study-design Quantitative - Prospective-cohort-study-using-pre-and post-implementation-comparison Qualitative-Semi-Structured-interviews **Interventions-**ePRO-smartphone-app

**Feasibility and Implementation: Primary endpoint** Feasibility-of-ePRO-**defined as** feasible if 75% of-participants-hospitalized >2 days completed >2 symptom-reports. **Secondary endpoint Patient-Reported-Symptom-Burden Length-Of-Hospital-Stay-And 30-Day-Readmission-Rates.**




**Conclusion:**

We aim to-incorporate ( ePRO ) into electronic medical records and analyze burden of disease in real-world setting and impact of interventions .

We plan a pilot-randomized-trial-to-assess-feasibility-and-preliminary-efficacy-of a symptom monitoring intervention using ePRO to improve symptom management in patients with gynecological malignancies who are admitted via emergency OPDs.

**PR020 / #1001**

**Topic:** *AS02. Clinical Disciplines / AS02d. Radiation Oncology*

## SUBLINGUAL MISOPROSTOL FOR CERVICAL PREPARATION IN BRACHYTHERAPY: A RANDOMIZED PHASE I/II TRIAL CONCEPT

**Presentation:** *Featured Printed Poster Presentation*

Rojine Ariani, Puja Venkat
University of California Los Angeles, Radiation Oncology, Los Angeles, United States of America

**Introduction:** Mechanical cervical dilation during brachytherapy tandem insertion can cause complications such as bleeding, cervical trauma, uterine perforation, and treatment delays. Misoprostol is routinely used off-label for cervical preparation; however, its role in brachytherapy has not been systematically investigated. This trial will evaluate whether misoprostol can improve procedural ease and reduce complications associated with tandem insertion in patients with cervical cancer.

**Objectives:** The primary objective is to assess the impact of sublingual misoprostol on procedural ease of tandem placement, measured by size of initial dilator and physician-graded tandem insertion difficulty. Secondary endpoints include rates of acute dilation-related toxicity (bleeding, cramping, uterine perforation, treatment delays) and misoprostol-related side effects.

**Trial Design:** This randomized, double-arm, phase I/II trial compares standard mechanical dilation versus 400 mcg sublingual misoprostol administered three hours prior to brachytherapy applicator placement (intervention). Procedural metrics and complications will be recorded at the time of procedure.

**Feasibility and Implementation:** This trial will be conducted at a high-volume center with infrastructure to support pragmatic integration. Misoprostol is inexpensive, widely available, shelf-stable, and easily administered, making it well-suited for implementation in high- and low-resource settings alike. It requires no specialized equipment or clinical training and integrates readily into standard workflows. Side effects are infrequent, mild, and self-limited at the dose proposed in this study.

**Conclusion:** This trial examines a scalable, pharmacologic strategy to support cervical dilation during tandem insertion for brachytherapy. By reducing procedural complexity and minimizing risk of dilation-related complications, misoprostol may improve safety and tolerability of brachytherapy for patients with cervical cancer.

**PR026 / #53**

**Topic:** *AS02. Clinical Disciplines / AS02e. Surgical Techniques & Perioperative Management*

## A SINGLE-ARM PROSPECTIVE TRIAL OF FLUORESCEIN MAPPING IN PATIENTS UNDERGOING VULVECTOMY FOR EXTRAMAMMARY PAGET'S DISEASE

**Presentation:** *Featured Printed Poster Presentation*

Clarissa Lam, Nadeem Abu-Rustum, Ahmed Al-Niaimi, Vance Broach, Dennis Chi, Jacqueline Feinberg, Ginger Gardner, Elizabeth Jewell, Sarah Kim, Kara Long Roche, Jennifer Mueller, Evan Smith, Yukio Sonoda, Mario Leitao Jr.
Memorial Sloan Kettering Cancer Center, Department Of Surgery, New York, United States of America

**Introduction:** Extramammary Paget's disease (EMPD) of the vulva is a rare neoplasm, with surgery being the standard treatment approach. However, EMPD cannot always be discerned by the naked eye. Our historical data demonstrate an 80% rate of positive surgical margin, associated with an increased recurrence risk. The use of intravenous (IV) fluorescein sodium was recently introduced for mapping before surgical excision to improve accuracy of resection.

**Objectives:** To investigate the use of IV fluorescein as a low-cost way to improve negative surgical margin rates and, subsequently, decrease recurrence risk in patients undergoing vulvectomy for EMPD.

**Trial Design:** This is a single-arm prospective trial. After standard anesthesia induction and positioning, the visible lesion will be delineated and 5 mL of 10% IV fluorescein injected. Fluorescence will be visualized using a Wood's lamp and a second outline made of the fluorescing area. This delineated lesion will be excised with a 1-cm margin if feasible. This trial uses only readily available resources, namely fluorescein and a Wood's lamp, and does not significantly increase operating time or risk to the patient.

**Feasibility and Implementation:** Implementation of this trial is feasible, as both IV fluorescein sodium and a Wood's lamp are readily available even in low-resource settings. Patients with multifocal EMPD will not be recruited. If complete resection requires resection of crucial structures, such as the clitoris, urethra, and/or anus, we will not attempt a negative-margin resection.

**Conclusion:** Vulvar EMPD is an understudied disease that requires appropriate treatment, including negative-margin resection if feasible, to decrease the risk of recurrence.

**PR080 / #712**

**Topic:** *AS06. Tumor Types / AS06d. Ovarian Cancer*

## INVESTIGATING THE EFFICACY OF OLANZAPINE ON WEIGHT GAIN AS AN ADJUNCT TO NEOADJUVANT CHEMOTHERAPY IN ADVANCED OVARIAN CANCER PATIENTS: A PLACEBO-CONTROLLED RANDOMIZED CONTROLLED TRIAL (O2 TRIAL)

**Presentation:** *Featured Printed Poster Presentation*

Jagannath Mishra[1], Subhashree Rout[1], Jaydip Bhaumik[1], Basumita Chakraborti[1], Somnath Roy[2], Anik Ghosh[1], Subir Sinha[3]
[1]Tata Medical Center, Gynaecological Oncology, Kolkata, India, [2]Tata Medical Center, Medical Oncology, Kolkata, India, [3]Tata Medical Center, Biostatistics, Kolkata, India

**Introduction:** Patients with advanced ovarian cancer experience weight loss due to early satiety and anorexia, compounded by chemotherapy-induced nausea and vomiting. Weight loss in advanced cancer is associated with reduced survival and quality of life. While some studies suggest that paclitaxel-based chemotherapy may lead to weight gain, evidence remains inconclusive. The GOG-158 trial observed that >5% weight gain correlated with improved survival; however, no pharmacological agent has yet been evaluated to improve weight. Olanzapine, known to stimulate appetite and weight gain in patients with schizophrenia as well as those with GI tract and lung cancers, remains unstudied in this setting.

**Objectives:** Primary: To compare the proportion of patients achieving >5% weight gain after 3–4 cycles of chemotherapy Secondary: To compare health-related quality of life using the Functional Assessment of Cancer Therapy-Ovarian questionnaires and grade 3-4 chemotherapy-related toxicities

**Trial Design:** Single centre, randomized, double-blind, placebo controlled phase III clinical trial

**Feasibility and Implementation:** Tata Medical Centre, Kolkata, is well-equipped with robust research infrastructure, an experienced team, and established data systems to conduct this trial. Challenges: 1. Although low awareness and skepticism toward clinical trials in LMICs like India may hinder recruitment, this will be addressed through structured counseling. Compliance with medication/placebo will be ensured through treatment diaries and collection of unused tablets after each chemotherapy cycle.
2. Funding support will be sought from national and international agencies.

**Conclusion:** The O2 trial explores a novel, low-cost intervention, olanzapine, to improve weight and quality of life in patients with advanced ovarian cancer receiving neoadjuvant chemotherapy.

**PP001 / #1010**

**Topic:** *AS02. Clinical Disciplines / AS02d. Radiation Oncology*

## VAGINAL DILATION PRIOR TO BRACHYTHERAPY TO REDUCE PROCEDURE-RELATED PSYCHOLOGICAL DISTRESS IN PATIENTS WITH ENDOMETRIAL CANCER: A RANDOMIZED PHASE I/II TRIAL CONCEPT

**Presentation:** *E-Poster Presentation*

Rojine Ariani, Puja Venkat
University of California Los Angeles, Radiation Oncology, Los Angeles, United States of America

**Introduction:** Vaginal cylinder brachytherapy (VBT) is a standard adjuvant treatment for endometrial cancer. Despite its clinical efficacy, the invasive nature of intracavitary device placement often contributes to procedural anxiety and distress. Current guidelines recommend initiating vaginal dilation (VD) 1 month after VBT to prevent vaginal stenosis. Introducing VD prior to treatment may reduce procedural distress associated with VBT, addressing both psychological and physical survivorship challenges.

**Objectives:** The primary objective is to evaluate patient-reported PTSD symptoms following adjuvant VBT using the PTSD Checklist for DSM-5. Secondary endpoints include VD adherence, quality-of-life and sexual health metrics (EORTC QLQ-C30, QLQ-EN24, QLQ-SH22) and radiation toxicity (CTCAE v6.0).

**Trial Design:** This randomized, double-arm, phase I/II trial compares standard-of-care VD initiated post-VBT versus VD initiated pre-VBT. The intervention arm will initiate VD 1-2 weeks prior to VBT, with structured education and adherence tracking. Both groups will receive standard guidance for post-VBT VD.

**Feasibility and Implementation:** This trial will be conducted at a high-volume center with infrastructure to support pragmatic integration. VD is a low-cost, low-complexity intervention requiring minimal equipment and provider training, making it suitable for routine care across diverse settings. It aligns with standard survivorship practices and can be incorporated into existing clinical workflows. Challenges to acceptability and adherence will be identified and addressed through structured education during follow-up.

**Conclusion:** This trial investigates a scalable, behavior-based intervention to reduce both psychological and physical morbidity associated with VBT. If effective, implementation of VD prior to VBT could offer a practical and equitable approach to improving survivorship outcomes in gynecologic cancer care.

**PP002 / #1115**

**Topic:** *AS06. Tumor Types / AS06b. Cervical Cancer*

## NEO ADJUVANT CHEMOIMMUNOTHERAPY FOLLOWED BY CHEMORADIATION AND MAINTENANCE IMMUNOTHERAPY FOR HIGH-RISK LOCALLY ADVANCED CERVICAL CANCER: A PHASE 3, RANDOMISED, OPEN LABEL STUDY

**Presentation:** *E-Poster Presentation*

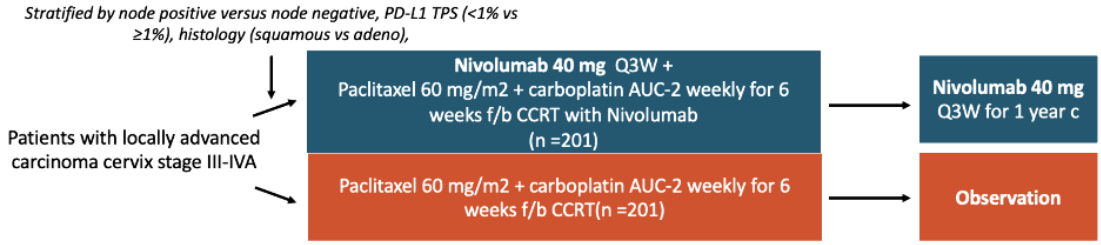
Sachin Khurana[1], Raja Pramanik[1], Prabhat Malik[1], Babita Kataria[1], Surendra Saini[2], Sushmita Pathy[2], Dayanand Sharma[2]
[1]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Department Of Medical Oncology, New Delhi, India, [2]ALL INDIA INSTITUTE OF MEDICAL SCIENCES, Department Of Radiation Oncology, New Delhi, India

**Introduction:** Patients of Stage III and IVA carcinoma cervix patients are at high risk of relapse and have frequent treatment failure with current standard of care that includes chemoradiation with or without pembrolizumab. High cost of immunotherapy is a deterrent especially in low resource settings and neoadjuvant chemotherapy trial included a heterogenous population with low risk patients also. This study aims to address this unmet need and endeavours to improve the outcomes in this difficult to treat subset of carcinoma cervix patients by giving neoadjuvant chemotherapy and low dose immunotherapy.

**Objectives:** Primary: To demonstrate superiority of neoadjuvant chemoimmunotherapy followed by CCRT and maintenance immunotherapy relative to neoadjuvant chemotherapy and CCRT by assessment of PFS Secondary: 1. To demonstrate superiority of neoadjuvant chemoimmunotherapy followed by CCRT and maintenance immunotherapy relative to neoadjuvant chemotherapy and CCRT by assessment of OS 2. To assess the Quality of Life (EORTC QLQ30 and Cervical Cancer Module (Cx24)

**Trial Design:** This will be a phase 3, randomised, open label, study comparing addition of low dose nivolumab to neoadjuvant chemotherapy followed by CCRT and maintenance nivolumab to neoadjuvant chemotherapy and CCRT alone.

- Randomized, open label, phase III trial




- **Primary endpoints**: PFS per investigator
- **Key secondary endpoints**: OS, Quality of life

**Feasibility and Implementation:** RT techniques may vary from institution to institution which can affect homegeneity of patient population.

**Conclusion:** In this study, we aim to use combination of chemotherapy and lower dose immunotherapy prior to definitive chemoradiation and then continued as maintenance in a subset of patients who are at high risk of relapse. Lower doses of immunotherapy will keep the overall cost of treatment under check while improving the efficacy.

**PP003 / #505**

**Topic:** *AS06. Tumor Types / AS06c. Endometrial & Uterine Corpus Cancers*

## PERITONEAL FLUID CYTOLOGY IN CARCINOMA ENDOMETRIUM-TO DO OR NOT TO DO; RENEWING THE KNOWN BY CORRELATION WITH MOLECULAR CLASSIFICATION.

**Presentation:** *E-Poster Presentation*

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**Introduction:** Peritoneal cytology is an important prognostic factor in carcinoma endometrium but still it is not included in its staging system. It has shown to affect survival and is also associated with other negative prognostic indicators like histopathology, grade, FIGO stage as well as aggressive histopathological types. But, its correlation with molecular subtypes is yet to be explored.

**Objectives:** Primary Objectives: To assess the correlation of peritoneal fluid cytology with molecular classification of endometrial cancers. Secondary Objectives: To assess the effect of peritoneal cytology on survival and quality of life.

**Trial Design:** Prospective observational study will be conducted on all patients of carcinoma endometrium who undergo primary staging surgery. Peritoneal fluid cytology and molecular classification will be done for all patients and the correlation between the two parameters and its influence on survival and quality of life will be analyzed. The adjuvant therapy offered to the patients will be closely monitored and if the same was influenced by fluid cytology reports will be noted.

**Feasibility and Implementation:** As peritoneal fluid cytology is the first step for staging surgery for endometrial carcinoma patients, this study is feasible and easy to implement.

**Conclusion:** Peritoneal fluid cytology is a vital prognostic factor for endometrial carcinoma and if the same is correlated with molecular classification, the risk stratification and the recommended adjuvant treatment for these patients will need to be upgraded. Also in aggressive histological endometrial carcinomas, peritoneal fluid cytology might find a place in the staging system in the near future.