

## IGCS19-0136

### 387 WOMEN'S SEXUALITY POST GYNAECOLOGICAL CANCER TREATMENT AT GROOTE SCHUUR HOSPITAL: A QUALITATIVE, DESCRIPTIVE STUDY USING A COMPREHENSIVE FRAMEWORK

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**Objectives** This study aimed to investigate women's experiences of their sexuality post gynaecological cancer treatment by using a comprehensive framework of sexuality, and, to understand how their sexual health needs can best be addressed as part of cancer care.

**Methods** The study made use of a qualitative descriptive design. Participants were recruited through purposive sampling at follow-up clinics within Groote Schuur Hospital's Gynaecology Unit. The final sample consisted of 35 women aged 29–35. All women had been diagnosed with one or more gynaecological cancer and treated with either surgery, chemotherapy, radiation or a combination of these. Data was collected using semi-structured, in-depth individual interviews in participants' home language. Pile sorting was used within the interviews to facilitate discussion about difficult topics. The data was analysed using thematic analysis.

**Results** The results are expected to provide thorough insight into women's sexual functioning and psycho-sexual well-being post treatment and how this affects their lives and relationships.

**Conclusions** Such information can help develop support programs to improve patients' quality of life post treatment. Furthermore, this research expands the qualitative literature relating to gynaecological cancers in South Africa.

## Trials in Progress

## IGCS19-0755

### 388 SHORT-COURSE HIPEC AT THE TIME OF INTERVAL DEBULKING SURGERY FOR HIGH TUMOR BURDEN OVARIAN CANCER: PRELIMINARY RESULTS OF A PIONEERING CLINICAL TRIAL IN BRAZIL

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**Objectives** To present the postoperative outcomes in our ongoing clinical trial.

**Methods** Cross-sectional analysis of early data from our phase 2 trial – an open-label, multicenter, single-arm trial on the safety and efficacy of neoadjuvant chemotherapy (NACT) followed by fast-track cytoreductive surgery (CRS) plus short-course HIPEC in advanced ovarian cancer (ClinicalTrials.gov: NCT02249013).

**Results** Fifteen patients with stage IIIB (n=1) or IIIC (n=14) epithelial malignancies were enrolled until July, 2019. The median (range) age was 46 years (19–67), with preoperative serum CA125 levels of 737.7U/mL (161.6–6550). The median number of NACT cycles was 3 (2–4), resulting in PCI scores of 11 (3–18) at the time of CRS/HIPEC – developed after 29 days (26–43) from the last NACT cycle. Time to restarts i.v. chemotherapy was 39 days (31–74). Median operation time was 490 minutes (235–865), with 9 patients requiring major bowel resection as rectosigmoidectomy (n=8) or partial colectomy (n=1). Median length of hospital stay was 5 days (3–10), with ICU stay of 1 day (1–5). Four patients experienced no postoperative complications, whereas 5 suffered only minor G1/G2 complications, and 6 suffered major G3 complications, according to the NCI/CTCAE classification. The most common complications were electrolytes imbalance and anemia. Two patients experienced reoperation because of G3 postoperative hemorrhage or peritoneal infection, whereas no deaths were recorded.

**Conclusions** Our protocol seems to be feasible and safe, with manageable low rates of short- and middle-term complications. Recruitment to this pioneering clinical trial in Brazil is ongoing.

## IGCS19-0447

### 389 SENTINEL NODE MAPPING WITH INDOCYANINE GREEN (ICG): INITIAL ANALYSIS OF PROSPECTIVE STUDY

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**Objectives** To report initial experience in Argentina using a local production ICG. Evaluating detection rates, incidence of nodal metastasis and adverse effects.

**Methods** Prospective non randomized single centre study that included patients with endometrial and cervical cancer (Surgical stages). The protocol and the informed consent were inscribed in Health National Research Register (RENIS). 1,25 mg/ml cervical injection of ICG (Laboratorio Bacon, Argentina) approved by ANMAT (National Administration of Drugs, Food and Technology) for use in this protocol. Karl Storz Image 1 S laparoscopic system was used and the technique was standardized by protocol.

**Results** 51 patients were included between July 2017–March 2019. 18 had low risk endometrial carcinoma and 17 high risk. In the 1st group we only performed SLN biopsy. In the high-risk group, we performed SNL plus lymphadenectomy. 16 patients had cervical cancer. At least one SLN was found in 98% (50/51) for ICG. Bilateral detection rate was 88%

(45/51) and most frequent localization was obturator basin. No serious adverse affect was reported. Incidence of macro-metastases was 19% (10/51), micrometastases 5,8% (3/51) and ITC 1,9% (1/51). No false negative SLN was found.

**Conclusions** ICG does not have approval in Argentina for any medical uses. This issue is frequent in regional countries in which infrared technology is available but ICG is not approved by local regulations. In this preliminary analysis using ICG in pharmacological test phase we found high bilateral detection, no false negative and no adverse effects in relation of ICG injection. This protocol is open recruiting patients.

## IGCS19-0188

### 390 COM701 (A NOVEL IMMUNE CHECKPOINT INHIBITOR) IN PATIENTS WITH ADVANCED SOLID TUMORS

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**Objectives** Novel therapies are needed for the treatment of pts with relapse/refractory disease following treatment with approved checkpoint inhibitors. COM701 is a 1st in class novel immune checkpoint inhibitor of PVRIG, part of the DNAM axis. Key primary objectives/endpoints: safety and tolerability of COM701 monotherapy and in combination with nivolumab (doublet), measured by the incidence of pts with adverse events (AEs) and dose-limiting toxicities (DLTs). The recommended dose for expansion of COM701 monotherapy and in combination with nivolumab. Key secondary objectives/endpoints: the preliminary antitumor activity of COM701 monotherapy and doublet in pts with selected tumor types (endometrial, ovarian, breast and lung cancer).

**Methods** Study design: dose escalation hybrid single subject accelerated titration design and 3+3 design. Key inclusion criteria: Age  $\geq 18$  yrs, histologically confirmed, advanced solid tumor and has exhausted all available standard therapy or not a candidate for available standard therapy, prior checkpoint inhibitor permissible. Key exclusion criteria: inflammatory pneumonitis, history of immune-related events that led to immunotherapy treatment discontinuation. We report on COM701 monotherapy dose escalation. Expansion cohorts will enroll pts with the selected tumor types (above). Clinical-Trials.gov Identifier: NCT03667716.

**Results** At time of this submission no DLTs observed up to 5th COM701 monotherapy dose level pt cohort.

**Conclusions** Study enrollment ongoing.

COM701 monotherapy safe and tolerable at the doses tested. Updated results will be presented at the meeting.

## IGCS19-0146

### 391 DEVELOPMENT OF THE COMPREHENSIVE SCORE FOR FINANCIAL TOXICITY (COST) TOOL AND ASSESSMENT OF FINANCIAL TOXICITY IN PATIENTS WITH GYNECOLOGIC CANCER IN JAPAN

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**Objectives** As new medical technology develops, medical costs increase. When high medical costs affect the patient as a toxicity, it is called financial toxicity (FT). In Japan, all patients are covered by the public health insurance system, which may alleviate FT. However, previous research using the Japanese version of the "Comprehensive Score for financial Toxicity (COST)" tool, whose score quantifies FT, showed that Japanese patients with cancer had FT. Our objective is to analyze its internal validity and the relationship between the COST score and patient information particularly for patients with ovarian, cervical, or endometrial cancer during chemotherapy. Furthermore, this study aims to clarify the correlation between COST and QOL scores.

**Methods** We will enroll 147 patients, including 49 patients each with ovarian, cervical, and endometrial cancers, from April 2019 to April 2020. Each patient will have been receiving chemotherapy for more than 2 months at enrollment. Each participant will answer the COST tool, EORTC-QLQ-C30, OV28/CX24/EN24, and EQ-5D-5L at baseline and at the end of chemotherapy. The patients will also complete a questionnaire about employment, assets, income, private insurance, medical payments in the last 2 months, presence of children or family members who need a caregiver, and consultation for medical payment before chemotherapy.

**Results** This research will clarify the characteristics and longitudinal changes in the COST score in gynecologic cancer patients. The impact of FT on the clinical situation will also be determined.

**Conclusions** We expect to find that the COST score can be used prospectively to improve QOL in patients with gynecologic cancer.