CERVICAL GLANDULAR INTRAEPITHELIAL NEOPLASIA; INCIDENCE, MANAGEMENT AND OUTCOMES OVER 1 YEAR IN A TERTIARY IRISH HOSPITAL

A double-blind, 4-block randomized, placebo-controlled, adaptive phase 2/3 trial consists of two parts. In phase 2, the optimal dose of BLS-ILB-E710c is determined based on the histopathological regression. In phase 3, the efficacy of BLS-ILB-E710c is assessed.

Results In a previous clinical trial, there was no difference in the rate of histopathological regression in the group taking the BLS-ILB-E710c 1000 mg per day compared to the placebo group at Week 16. However, in the sub-group analysis of CIN 3 patients, the rate of histopathological regression in the experimental group increased statistically significantly at Week 32 compared to Week 16. Additionally, a significant change in CD8+ T cells in the cervix was observed in the experimental group at Week 32. Based on these results, we'll add a group taking BLS-ILB-E710c 1500 mg per day and confirm the histopathological regression at week 32 instead of week 16.

Conclusions Conclusion/Implications - In order to improve the results of the existing clinical trial, stratified randomization will be performed using age and baseline CIN as factors. Additionally, to discover biomarkers of CIN, an extension study will be conducted only on patients with histopathological regression.

Methods Safety and efficacy of BLS-ILB-E710c are assessed in a double-blind, 4-block randomized, placebo-controlled, seamless two-part, adaptive phase 2/3 study. The adaptive phase 2/3 trial consists of two parts. In phase 2, the optimal dose of BLS-ILB-E710c is determined based on the histopathological regression. In phase 3, the efficacy of BLS-ILB-E710c is assessed.

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Conclusions Younger patients, especially those below 39 years old, are more likely to achieve CR. Value of medical treatment beyond 9 months needs to be re-evaluated.

EP326/#898 ORAL PROGESTINS VS LEVONORGESTREL-RELEASING INTRAUTERINE SYSTEM IN TREATMENT OF ATYPICAL ENDOMETRIAL HYPERPLASIA

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Objectives This study aims to compare the treatment efficacy of oral progestins vs levonorgestrel-releasing intrauterine system (LNG-IUS) in patients with atypical endometrial hyperplasia (AEH).

Methods This is a retrospective study conducted in a single tertiary hospital in Singapore. Women diagnosed with AEH on endometrial biopsy between January 2015 to October 2017, and treated with at least 8 weeks of the same progestin were included. Statistical analysis was performed with Pearson χ² test, Fisher exact test or independent sample t test as appropriate.

Results 42 patients met the inclusion criteria, of which 37 were treated with oral progestins and 5 with LNG-IUS. Median follow up was 39 months (range 2–72). Age of diagnosis was significantly lower in patients who were treated with LNG-IUS as compared to oral progestin (34.20 ± 5.357 vs 42.32 ± 6.654, p=0.013). There was no significant difference in mean body mass index (30.44 ± 8.11 vs 36.40 ± 9.409, p=0.490), parity (p=0.591), diabetes mellitus (8/37 vs 3/5, p=0.103), and polycystic ovarian syndrome (3/37 vs 1/5, p=0.410). There was no significant difference in mean time (months) to regression (7.26 ± 5.68 vs 6.6 ± 1.95, p=0.802). All 5 patients treated with LNG-IUS had complete regression with no recurrence, but this was not significantly different as compared to those treated with oral progestins (regression rate 5/5 vs 23/37, p=0.138; recurrence rate 0/5 vs 8/23, p=0.119).

Conclusions There was no significant difference in treatment outcomes with oral progestins as compared to LNG-IUS.

EP328/#979 CYTOTOLOGY AND HPV DNA CERVICAL CANCER SCREENING IN HIV POSITIVE AND HIV NEGATIVE WOMEN

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Objectives HPV-testing is becoming the preferred cervical cancer screening test. Data on HPV DNA screening in resource poor settings are limited. The objectives were to investigate cytology and primary HPV screening in women living with HIV and HIV negative women.

Methods Study was performed in two academic centres in South Africa. Patients had cytology and HPV testing (Hybrid Capture-2, HC2). Those with positive tests had colposcopy and punch biopsy or loop excision of the transformation zone (LETZ). Data were imputed using a statistical model which maintained the underlying distribution of the available results, allowing calculation for the total screening population.

Results Included were 909 women with mean age 41.42 years (SD 9.82; 25–65 years). In 903 women with known HIV status, 683(75.64%) had negative cytology and 202(22.37%) had abnormal cytology. HC2 HPV was negative in 621(68.77%) women. In WLWH, 54.48% tested cytology negative compared to 79.69% in HIV negative women (p<0.0001). HC2 HPV screening had higher sensitivity (60.92%), but lower specificity (82.39%) compared to cytology (48.59% and 86.75%) for detection of CIN 2+ in all women, except in HIV negative women, where HC2 HPV specificity (75.00%) was