Objective: To assess the characteristics of the CGIN patient cohort diagnosed in the Rotunda Colposcopy Unit. To identify the number of patients referred with and diagnosed with CGIN in our unit in 1 year. To establish the outcomes of all cases of CGIN in our unit.

Methods: Audit approval was obtained from the Rotunda Clinical Audit Department. In the Rotunda Colposcopy Unit, all cases of CGIN are discussed at MDT. A list of all cases of CGIN diagnosed in our unit in 2021 was established from Colposcopy MDT reports. A retrospective chart review was performed. Data was collected and analysed using Microsoft Excel.

Results: 2073 women were referred to the Rotunda Colposcopy Unit in 2021, 12 of whom were diagnosed with CGIN giving an incidence of 0.6%. 75% (n=9) women had High Grade cytological changes on their referral cervical smear, and 25% (n=3) had Low Grade changes. 83% (n=10) patients were diagnosed via cervical punch biopsy and the remaining 2 patients were diagnosed via LLETZ. 3 patients underwent 1 LLETZ procedure, 6 patients underwent 2 LLETZ, and 3 patients had 1 LLETZ followed by Hysterectomy. 3 patients underwent Total Laparoscopic Hysterectomy, one of whom was referred to Gynaec-oncology with SCC in situ. 1 patient has had her second TOC, 5 patients have had their first TOC, and 3 patients are awaiting their first TOC.

Conclusions: The HPV screening programme is detecting CGIN, which is universally associated with HPV and high grade squamous abnormalities. Treatment of CGIN is complex and supported by MDT involvement.

Objective: Current treatments for cervical intraepithelial neoplasia 2/3(CIN 2/3) are ablative, so non-invasive treatments are needed as alternatives. For the development of alternative treatment, we designed adaptive phase 2/3 trial to confirm efficacy of BLS-ILB-E710c in patients with CIN 2/3.

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.

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 will 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.