

A Study of the Clinical Impact of a Three Month Pre-Operative Course of Ulipristal Acetate in Subjects with Known Pelvic Endometriosis.

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Introduction

Progesterone is central to the pathogenesis of endometriosis and prolonged exogenous progesterone therapy can be effective as medical management. Progesterone receptor modulators are known to have an anti-proliferative effect on eutopic endometrium. Our study was designed to assess the clinical impact of Ulipristal acetate on symptoms and quality of life.

Materials & methods

The CHUTE (Changes in Histology following Ulipristal Treatment in Endometriosis) trial is an interventional descriptive cohort study of 20 subjects with pelvic endometriosis confirmed by laparoscopy. Administration of Ulipristal Acetate (5mg) once daily for three months prior to surgical management of the disease allowed assessment of clinical and histological changes.

Study participants were assessed using the Endometriosis Health Profile Questionnaire (EHP-30) at screening, during the final week of treatment and 6 weeks after treatment at the pre-operative visit. In addition, a Patients' Global Impression of Change (PGIC) questionnaire was also used to assess effectiveness from a patient perspective.

Results

A total of 18 patients completed the study with two exclusions. A positive response to Ulipristal Acetate (UPA) has been seen in the majority of the patients (16/18) with the drug well tolerated.

The EHP-30 scores were significantly better whilst taking UPA ($t= 4.482$, $p<0.001$) and this was maintained ($t= 3.304$, $p=0.004$) following cessation of the drug. More specifically, the pain domain questions in the EHP-30 questionnaire show marked improvement on UPA ($t= 4.751$, $p<0.001$) that is again maintained after completion ($t= 3.269$, $p=0.005$).

Using the PGIC questionnaire to categorise the degree of response to UPA we identified a sub-group of strong responders (10/18). The EHP-30 scores for this sub-group show a dramatic ($t= 7.906$, $p<0.001$) and maintained ($t= 2.283$, $p=0.048$) response to UPA.

Conclusion

Ulipristal acetate appears to be an effective medical treatment for endometriosis, which is maintained after treatment cessation. Whilst there is a range of clinical responses the majority of patients demonstrate improvements in both pain and quality of life scores.

Keywords : Endometriosis, Ulipristal acetate, Histopathology

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